CBER Requested Tables
mRNA-1273

BLA Application #125752

CONFIDENTIAL

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1 Clinical Trial Overview

Table 1: (Table A) Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Moderna COVID-19 Vaccine mRNA-1273

Study Number	Type of Study (Efficacy, Safety, Nonclinical)	Population (N)	Study Design and Type of Control	Test Product(s); Dosing Regimens; Dosage Forms; Routes of Administration; Duration	Study Status
DMID 20-0003	Safety Immunogenicity	Men and nonpregnant women at least 18 years of age, in good health (120)	Open-label, dose-ranging	10[a], 25, 50, 100, and 250 µg IM injection mRNA-1273 2 doses, 28 days apart	Ongoing
mRNA-1273-P201	Safety Immunogenicity	Men and nonpregnant women at least 18 years of age, in good health (600)	Randomized, observer-blind, placebo-controlled	50 or 100 µg IM injection mRNA-1273 2 doses, 28 days apart	Ongoing
mRNA-1273-P301	Safety Efficacy	**Part A** Men and nonpregnant women at least 18 years of age, at appreciable risk of SARS-CoV-2 infection, with a negative history for SARS-CoV-2 infection (30,346)	Case-driven, randomized, stratified, observer-blind, placebo-controlled	100 µg of mRNA-1273 or placebo 2 doses, 28 days apart	Ongoing

		Part B Men and nonpregnant women at least 18 years of age (28,964) Must have previously enrolled in mRNA-1273-P301 (Part A participants who had received 1 dose of 100 µg mRNA-1273 or placebo)	Open-label, observational	100 µg of mRNA-1273 2 doses, 28 days apart[b]	

Abbreviations: IM=intramuscular; N=number of participants; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

[a] The 10 µg cohort was not enrolled.

[b] One dose in some participants: participants who were unblinded at the participant decision visit and who received ONLY 1 dose of mRNA-1273 100 µg in Part A, were eligible to receive a second dose of mRNA-1273 in Part B if they met certain criteria.

Source: Adapted from STN 125752.1_ Module 5.2.

2 Disposition

Table 2: (Table B) Study Disposition (Safety Set)

	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Safety Set	N=15184	N=15162	N=30346
Solicited Safety Set	15179 (>99.0)	15159 (>99.9)	30338 (>99.9)
First Injection Solicited Safety Set	15166 (99.9)	15151 (>99.9)	30317 (>99.9)
Second Injection Solicited Safety Set	14691 (96.8)	14578 (96.1)	29269 (96.5)
Original blinded, placebo-controlled follow-up period			
Completed 1 dose	15184 (100)	15162 (100)	30346 (100)
Completed 2 doses	14731 (97.0)	14631 (96.5)	29362 (96.8)
Median blinded follow-up [a]	148.0	146.0	148.0
Completed at least 6 months follow-up post dose 2 in blinded phase	7499 (49.4)	6778 (44.7)	14277 (47.0)
Discontinued from study vaccine (original blinded placebo-controlled phase /Part A)	453 (3.0)	531 (3.5)	984 (3.2)
Reason for discontinuation of study vaccine			
Adverse event	47 (0.3)	44 (0.3)	91 (0.3)
Serious adverse event	12 (<0.1)	18 (0.1)	30 (<0.1)
Death	2 (<0.1)	3 (<0.1)	5 (<0.1)
Loss to follow-up	76 (0.5)	73 (0.5)	149 (0.5)
Physician decision	21 (0.1)	18 (0.1)	39 (0.1)
Pregnancy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Protocol deviation	37 (0.2)	37 (0.2)	74 (0.2)
Withdrawal of consent by participant	78 (0.5)	108 (0.7)	186 (0.6)
Due to SARS-CoV-2	81 (0.5)	119 (0.8)	200 (0.7)
Other	94 (0.6)	104 (0.7)	198 (0.7)
Discontinued after dose 1 and before dose 2	453 (3.0)	531 (3.5)	984 (3.2)
Discontinued/Withdrawn from study	701 (4.6)	2059 (13.6)	2760 (9.1)
Reason for withdrawal from study			
Adverse event	4 (<0.1)	5 (<0.1)	9 (<0.1)
Serious adverse event	5 (<0.1)	4 (<0.1)	9 (<0.1)
Death	24 (0.2)	19 (0.1)	43 (0.1)
Lost to follow-up	171 (1.1)	199 (1.3)	370 (1.2)
Physician decision	16 (0.1)	13 (<0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol deviation	151 (1.0)	664 (4.4)	815 (2.7)
Withdrawal of consent by participant	266 (1.8)	426 (2.8)	692 (2.3)
Other	63 (0.4)	728 (4.8)	791 (2.6)

	Original treatment group: mRNA-1273 (N=15184) n (%)	**Original treatment group: Placebo (N=15162) n (%)**	**Total* (N=30346) n (%)**
Open-label follow up period			
Started Open-label phase	N=14618	N=14346	N=28964
Remain on original arm	N=14618	N=1698	N=16316
Placebo participants crossed over to receive mRNA-1273		N=12648	
Completed dose 3	NA	12648 (100.0)	NA
Completed dose 4	NA	11757 (93.0)	NA
	mRNA-1273 (N=15184) n (%)	**Placebo-mRNA-1273 (N=12648) n (%)**	**Total* (N=30346) n (%)**
Discontinued from study	290 (1.9)	51 (0.4)	1698 (5.6)
Reason for discontinuation			
Adverse event	1 (<0.1)	0	1 (<0.1)
Serious adverse event	0	1 (<0.1)	1 (<0.1)
Death	8 (<0.1)	3 (<0.1)	12 (<0.1)
Lost to follow-up	11 (<0.1)	3 (<0.1)	21 (<0.1)
Physician decision	5 (<0.1)	3 (<0.1)	15 (<0.1)
Pregnancy	1 (<0.1)	0	2 (<0.1)
Protocol deviation	106 (0.7)	11 (<0.1)	610 (2.0)
Study terminated by sponsor	0	0	0
Withdrawal of consent by participant	124 (0.8)	23 (0.2)	322 (1.1)
Due to SARS-CoV-2	0	0	0
Other	34 (0.2)	7 (<0.1)	714 (2.4)

Abbreviations: N=number of subjects in analysis set; PDV=Participant Decision Visit; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

[a] Includes participants who had PDV/unblinding on/before data cutoff date.

* For open-label /Part B, Total column represents the total over the 3 groups in Open-label phase: mRNA-1273 (those received mRNA-1273 in Blinded Phase/Part A), Placebo-mRNA-1273 (those received Placebo in Part A and crossed over to mRNA-1273 in Open-label Phase/Part B), and Placebo (those received Placebo in Part A and did not cross over). The Placebo group in Part B is not presented in this table.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.1.2.1, Table 14.1.1.1.5.1, Table 14.1.6.2.1; mRNA-1273-P301 Clinical Study Report Addendum 1 (Part B), Table 14.1.1.1.5.5.

Table 3: (Table C) Study Disposition, Efficacy Analysis Populations

	mRNA-1273 n (%)	Placebo n (%)	Total n (%)
Randomized	N=15209	N=15206	N=30415
Full Analysis Set	N=15180	N=15166	N=30346
mITT Set	N=14746	N=14745	N=29491
PP Set[a]	N=14297	N=14164	N=28451
Excluded from PP Set	459 (3.0)	581 (3.8)	1040 (3.4)
Reason for exclusion[b]			
Received incorrect study vaccination	6 (<0.1)	7 (<0.1)	13 (<0.1)
Discontinued study or study vaccination before receiving second injection	334 (2.2)	425 (2.8)	759 (2.5)
Received second injection out of window for PP Set	102 (0.7)	119 (0.8)	221 (0.7)
Not received second injection and passed the window for PP Set	0	0	0
Other major protocol deviation impacting critical data	17 (0.1)	30 (0.2)	47 (0.2)
PP Immunogenicity Subset[a]	N=1185	N=272	N=1457
Excluded from PP Immunogenicity Subset	71 (5.7)	63 (18.8)	134 (8.4)
Reason for exclusion[b]			
Received incorrect vaccination	0	1 (0.3)	1 (<0.1)
Received dose 2 out of window for PP Set	5 (0.4)	3 (0.9)	8 (0.5)
Did not receive dose 2 per schedule	44 (3.5)	52 (15.5)	96 (6.0)
Human Immunodeficiency Virus Infection	21 (1.7)	4 (1.2)	25 (1.6)
Had other major protocol deviations	1 (<0.1)	3 (0.9)	4 (0.3)

Abbreviations: IP=investigational product; mITT=modified intent-to-treat; N=number of participants in the analysis set; PP=per-protocol.

Notes: The randomized set consists of all participants who were randomized, regardless of the participant's treatment status in the study.

The full analysis set consists of all randomized participants who received at least 1 dose of IP.

The mITT set consists of all participants in the full analysis set who had no immunologic or virologic evidence of prior COVID-19 (negative SARS-CoV-2 status, ie, negative NP swab test and negative bAb against SARS CoV-2 N-protein as measured by Roche Elecsys) at Day 1 before the first dose of IP.

The PP set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data. The PP set was the primary analysis population for efficacy analyses, unless otherwise specified.

The PP immunogenicity subset consisted of of participants in the FAS who were sampled into the random subcohort and a) received both planned doses (ie, received the treatment as the participant was randomized to) with Dose 2 received within [21, 42] days after Dose 1, and b) no major protocol deviation that impacted critical or key data.

[a] Percentages are based on the number of participants in the analysis set.

[b] A participant who has multiple reasons for exclusion is listed under the reason that appears earliest.

Source: Adapted from mRNA-1273 P301 Clinical Study Report Table 14.1.2.3, Table 14.1.2.4, Table 14.1.2.5.

Table 4: (Table D) Follow-up (Safety Set)

	mRNA-1273 (N=15184)	Placebo (N=15162)	Total (N=30346)
Follow-up during blinded phase			
Median blinded follow-up post dose 2, days			
All participants	118	114	116
≥18 to <65 years	118	114	116
≥65 years	118	115	116
At least 2 months blinded follow-up post dose 2, n (%)	14342 (94.5)	14170 (93.5)	28512 (94.0)
Between 2 to <4 months follow-up post dose 2, n (%)	7819 (51.5)	8342 (55.0)	16161 (53.3)
At least 4 months blinded follow-up post dose 2, n (%)	6523 (43.0)	5828 (38.4)	12351 (40.7)
Between 4 to <6 months follow-up post dose 2, n (%)	6370 (42.0)	5670 (37.4)	12040 (39.7)
At least 6 months blinded follow-up post dose 2, n (%)	153 (1.0)	158 (1.0)	311 (1.0)
Follow up during open-label phase			
Median total follow-up (blinded + unblinded) after dose 2 of originally assigned treatment, days			
All participants	183	180	182
≥18-65 years	183	178	180
≥65 years	185	184	185
At least 6 months total follow up (blinded + unblinded) after dose 2 of originally assigned treatment, n (%)	7499 (49.4)	6778 (44.7)	14277 (47.0)
Participants originally assigned to placebo and crossed over to receive mRNA-1273		**Placebo-mRNA-1273 (N=12648)**	
Received 2 doses of mRNA-1273, n (%)		11757 (93.0)	
Median follow-up post dose 4[a] (2 doses of mRNA-1273), days			
All participants		38	
≥18 to <65 years		37	
≥65 years		43	
At least 2 months follow-up post dose 4, n/N (%)			
All participants		39/11757 (0.3)	
≥18 to <65 years		31/8448 (0.4)	
≥65 years		8/3309 (0.2)	

Abbreviations: N=number of participants in analysis set.

Notes: 1 month=30.4375 days. Percentages are based on the number of safety participants. Study duration from dose 2 is 0 days for participants who did not receive dose 2.

[a] Follow-up post dose 4 is calculated as earlier date of discontinuation from study or 26 Mar 2021 – date of dose 4 + 1.

Source: Adapted from mRNA-1273-P301 P301 Clinical Study Report Table 14.1.6.2.1, Table 14.1.6.2.3; mRNA-1273-P301 Clinical Study Report Addendum 1 (Part B), Table 14.1.1.1.5.5.

3 Background Characteristics

Table 5: (Table E) Demographics and Other Baseline Characteristics (Safety Set)

Characteristic	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Sex			
Female	7266 (47.9)	7106 (46.9)	14372 (47.4)
Male	7918 (52.1)	8056 (53.1)	15974 (52.6)
Age (years)			
Mean [SD]	51.4 [15.51]	51.3 [15.60]	51.4 [15.55]
Median	53.0	52.0	52.0
Min, Max	18, 95	18, 95	18, 95
Age subgroups (years)			
≥18 to <65	11415 (75.2)	11411 (75.3)	22826 (75.2)
≥65 and older	3769 (24.8)	3751 (24.7)	7520 (24.8)
Race			
American Indian or Alaska Native	113 (0.7)	121 (0.8)	234 (0.8)
Asian	656 (4.3)	739 (4.9)	1395 (4.6)
Black or African American	1567 (10.3)	1531 (10.1)	3098 (10.2)
Native Hawaiian or other Pacific Islander	36 (0.2)	32 (0.2)	68 (0.2)
White	12034 (79.3)	11998 (79.1)	24032 (79.2)
Multiracial	320 (2.1)	318 (2.1)	638 (2.1)
Other	299 (2.0)	294 (1.9)	593 (2.0)
Not reported	97 (0.6)	74 (0.5)	171 (0.6)
Unknown	62 (0.4)	55 (0.4)	117 (0.4)
Ethnicity			
Hispanic or Latino	3122 (20.6)	3108 (20.5)	6230 (20.5)
Not Hispanic or Latino	11920 (78.5)	11918 (78.6)	23838 (78.6)
Not reported	105 (0.7)	83 (0.5)	188 (0.6)
Unknown	37 (0.2)	53 (0.3)	90 (0.3)
Occupational risk			
Healthcare worker	3809 (25.1)	3840 (25.3)	7649 (25.2)
High risk conditions			
One high risk condition present	2791 (18.4)	2815 (18.6)	5606 (18.5)
Two or more high risk conditions present	657 (4.3)	642 (4.2)	1299 (4.3)
No high risk condition	11736 (77.3)	11705 (77.2)	23441 (77.2)
BMI: <30 kg/m^2	9276 (61.1)	9300 (61.3)	18576 (61.2)
BMI: ≥30 kg/m^2	5820 (38.3)	5777 (38.1)	11597 (38.2)
Age and health risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	8890 (58.5)	8880 (58.6)	17770 (58.6)
≥18 to <65 years and at risk	2530 (16.7)	2535 (16.7)	5065 (16.7)
≥65 years	3764 (24.8)	3747 (24.7)	7511 (24.8)

Characteristic	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Baseline SARS-CoV-2 status[b]			
Negative	14750 (97.1)	14741 (97.2)	29491 (97.2)
Positive	347 (2.3)	337 (2.2)	684 (2.3)
Missing	87 (0.6)	84 (0.6)	171 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; IRT=Interactive Response Technology; Max=maximum; Min=minimum; N=number of participants in the safety set; n=number of participants in the category; RT-PCR=reverse transcriptase polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SD=standard deviation.

Note: The safety set consists of all randomized participants who received at least 1 dose of IP.

[a] Based on stratification factor from IRT, participants who are <65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[b] Baseline SARS-CoV-2 status: positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.1.3.2.3.

Table 6: (Table E) Demographics and Other Baseline Characteristics (Per-Protocol Set)

Characteristic	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Sex			
Female	6848 (47.9)	6670 (47.1)	13518 (47.5)
Male	7439 (52.1)	7494 (52.9)	14933 (52.5)
Age (years)			
Mean [SD]	51.6 [15.44]	51.6 [15.55]	51.6 [15.49]
Median	53.0	52.0	53.0
Min, Max	18, 95	18, 95	18, 95
Age subgroups			
≥18 to <65 years	10661 (74.6)	10569 (74.6)	21230 (74.6)
≥65 years	3626 (25.4)	3595 (25.4)	7221 (25.4)
Race			
American Indian or Alaska Native	109 (0.8)	113 (0.8)	222 (0.8)
Asian	628 (4.4)	700 (4.9)	1328 (4.7)
Black or African American	1395 (9.8)	1352 (9.5)	2747 (9.7)
Native Hawaiian or other Pacific Islander	36 (0.3)	31 (0.2)	67 (0.2)
White	11391 (79.7)	11273 (79.6)	22664 (79.7)
Multiracial	300 (2.1)	304 (2.1)	604 (2.1)
Other	282 (2.0)	274 (1.9)	556 (2.0)
Not reported	90 (0.6)	65 (0.5)	155 (0.5)
Unknown	56 (0.4)	52 (0.4)	108 (0.4)

Characteristic	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Ethnicity			
Hispanic or Latino	2831 (19.8)	2787 (19.7)	5618 (19.7)
Not Hispanic or Latino	11322 (79.2)	11249 (79.4)	22571 (79.3)
Not reported	99 (0.7)	76 (0.5)	175 (0.6)
Unknown	35 (0.2)	52 (0.4)	87 (0.3)
Occupational risk			
Healthcare worker	3631 (25.4)	3621 (25.6)	7252 (25.5)
High risk conditions			
One high risk condition present	2660 (18.6)	2610 (18.4)	5270 (18.5)
Two or more high risk conditions present	623 (4.4)	602 (4.3)	1225 (4.3)
No high risk condition	11004 (77.0)	10952 (77.3)	21956 (77.2)
BMI: <30 kg/m^2	8741 (61.2)	8719 (61.6)	17460 (61.4)
BMI: ≥30 kg/m^2	5460 (38.2)	5365 (37.9)	10825 (38.0)
Age and health risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	8271 (57.9)	8242 (58.2)	16513 (58.0)
≥18 to <65 years and at risk	2395 (16.8)	2331 (16.5)	4726 (16.6)
≥65 years	3621 (25.3)	3591 (25.4)	7212 (25.3)
Baseline SARS-CoV-2 status[b]			
Negative	14287 (100.0)	14164 (100.0)	28451 (100.0)
Positive	0	0	0

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; Max=maximum; Min=minimum; N=number of participants in the per-protocol set; n= n=number of participants in the category; RT-PCR=reverse transcriptase polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SD=standard deviation.

Note: The per-protocol set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data.

[a] Based on stratification factor from IRT, participants who are <65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[b] Baseline SARS-CoV-2 status: positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RTPCR test and negative Elecsys result at Day 1.

Source: Adapted mRNA-1273-P301 Clinical Study Report Table 14.1.3.4.3.

Table 7: (Table F) Protocol-Defined Risk for Severe COVID-19 Disease (Safety Set)

Risk category	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Without any protocol risk for severe COVID-19	11736 (77.3)	11705 (77.2)	23441 (77.2)
With any protocol risk for severe COVID-19[a]	3448 (22.7)	3457 (22.8)	6905 (22.8)
Chronic lung disease	712 (4.7)	749 (4.9)	1461 (4.8)
Significant cardiac disease	762 (5.0)	742 (4.9)	1504 (5.0)
Severe obesity	1070 (7.0)	1058 (7.0)	2128 (7.0)
Diabetes	1460 (9.6)	1457 (9.6)	2917 (9.6)
Liver disease	104 (0.7)	96 (0.6)	200 (0.7)
HIV infection	94 (0.6)	91 (0.6)	185 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; IP=investigational product; N=number of participants in the safety set; n=number of participants in the category.

Note, the safety set consists of all randomized participants who received at least 1 dose of IP.

[a] Participants could be under one or more categories, and are counted once at each category.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.1.3.2.3.

Table 8: (Table F) Protocol-Defined Risk for Severe COVID-19 Disease (Per-Protocol Set)

Risk category	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Without any protocol risk for severe COVID-19	11004 (77.0)	10952 (77.3)	21956 (77.2)
With any protocol risk for severe COVID-19[a]	3283 (23.0)	3212 (22.7)	6495 (22.8)
Chronic lung disease	675 (4.7)	692 (4.9)	1367 (4.8)
Significant cardiac disease	726 (5.1)	696 (4.9)	1422 (5.0)
Severe obesity	1009 (7.1)	980 (6.9)	1989 (7.0)
Diabetes	1402 (9.8)	1363 (9.6)	2765 (9.7)
Liver disease	100 (0.7)	90 (0.6)	190 (0.7)
HIV infection	85 (0.6)	82 (0.6)	167 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; IP=investigational product; N=number of participants in per-protocol set; n=number of participants in the category.

Note: The per-protocol set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data.

[a] Participants could be under one or more categories, and are counted once at each category.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.1.3.4.3.

4 Efficacy Analysis

Table 9: (Table G) Final Blinded Efficacy Analysis of Primary Endpoint, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

Primary Endpoint: COVID-19 (per adjudication committee assessment)	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=14164; Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
All participants	55/14287 (0.4); 9.599	744/14164 (5.3); 136.633	0.932 (0.910, 0.948)
≥18 to <65 years	46/10661 (0.4); 10.742	644/10569 (6.1); 158.958	0.934 (0.911, 0.951)
≥65 years	9/3626 (0.2); 6.217	100/3595 (2.8); 71.744	0.915 (0.832, 0.957)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.1.3.1.1, Table 14.2.2.1.3.6.1.1.

Table 10: (Table H) Subgroup Analysis of Final Efficacy Analysis, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=14164 Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Age			
≥18 to <65 years	46/10661 (0.4); 10.742	644/10569 (6.1); 158.958	0.934 (0.911, 0.951)
≥65 to <75 years	9/2990 (0.3); 7.546	81/2898 (2.8); 71.980	0.897 (0.796, 0.949)
≥75 years	0/636; 0.000	19/697 (2.7); 70.755	1.000 (NE, 1.000)
Age and risk for severe COVID-19			
≥18 to <65 years and not at risk	35/8464 (0.4); 10.320	501/8428 (5.9); 155.593	0.935 (0.909, 0.954)
≥18 to <65 years and at risk	11/2197 (0.5); 12.346	143/2141 (6.7); 171.991	0.930 (0.870, 0.962)
≥65 years and not at risk	4/2540 (0.2); 3.960	66/2524 (2.6); 67.598	0.943 (0.843, 0.979)
≥65 years and at risk	5/1086 (0.5); 11.428	34/1071 (3.2); 81.439	0.864 (0.653, 0.947)
Sex			

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	**Placebo N=14164 Cases /n (%); Incidence rate per 1,000 person-years**	**Vaccine Efficacy % (95% CI)**
Female	25/6848 (0.4); 9.078	366/6670 (5.5); 142.186	0.938 (0.907, 0.959)
Male	30/7439 (0.4); 10.081	378/7494 (5.0); 131.656	0.925 (0.891, 0.948)
Race			
American Indian or Alaska Native	0/109; 0.000	5/113 (4.4); 122.198	1.000 (NE, 1.000)
Asian	1/628 (0.2); 4.312	29/700 (4.1); 118.005	0.965 (0.742, 0.995)
Black or African American	4/1395 (0.3); 7.505	41/1352 (3.0), 82.452	0.911 (0.752, 0.968)
Native Hawaiian or other Pacific Islander	0/36; 0.000	0/31; 0.000	NE (NE, NE)
White	48/11391 (0.4); 10.345	631/11273 (5.6); 143.155	0.930 (0.906, 0.947)
Multiracial	1/300 (0.3); 8.960	8/304 (2.6); 73.736	0.881 (0.046, 0.985)
Other	1/282 (0.4); 9.677	19/274 (6.9); 203.829	0.958 (0.686, 0.994)
Not reported	0/90; 0.000	5/65 (7.7); 211.396	1.000 (NE, 1.000)
Unknown	0/56; 0.000	6/52 (11.5); 364.097	1.000 (NE, 1.000)
Ethnicity			
Hispanic or Latino	10/2831 (0.4); 9.202	177/2787 (6.4); 174.817	0.948 (0.902, 0.973)
Not Hispanic or Latino	45/11322 (0.4); 9.807	563/11249 (5.0); 128.417	0.926 (0.900, 0.945)
Not reported	0/99; 0.000	2/76 (2.6); 66.725	1.000 (NE, 1.000)
Unknown	0/35; 0.000	2/52 (3.8); 107.537	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.1.3.6.2.1, Table 14.2.2.1.3.6.4.1, Table 14.2.2.1.3.6.11.1, Table 14.2.2.2.3.6.5.1, Table 14.2.2.2.3.6.6.1.

Table 11: (Table I) Demographic Characteristics of Participants with COVID-19 Based on Adjudication Committee Assessments Starting 14 days after Dose 2, Based on Final Efficacy Analysis (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=55; n (%)	Placebo N=744; n (%)	Total N=799; n (%)
Age			
≥18 to <65 years	46 (83.6)	644 (86.6)	690 (86.4)
≥65 to <75 years	9 (16.4)	81 (10.9)	90 (11.3)
≥75 to <85 years	0	15 (2.0)	15 (1.9)
≥85 years	0	4 (0.5)	4 (0.5)
Age and risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	35 (63.6)	501 (67.3)	536 (67.1)
≥18 to <65 years and at risk	11 (20.0)	143 (19.2)	154 (19.3)
≥65 years and not at risk	4 (7.3)	66 (8.9)	70 (8.8)
≥65 years and at risk	5 (9.1)	34 (4.6)	39 (4.9)
Sex			
Female	25 (45.5)	366 (49.2)	391 (48.9)
Male	30 (54.5)	378 (50.8)	408 (51.1)
Race			
American Indian or Alaska Native	0	5 (0.7)	5 (0.6)
Asian	1 (1.8)	29 (3.9)	30 (3.8)
Black or African American	4 (7.3)	41 (5.5)	45 (5.6)
Native Hawaiian or other Pacific Islander	0	0	0
White	48 (87.3)	631 (84.8)	679 (85.0)
Multiracial	1 (1.8)	8 (1.1)	9 (1.1)
Other	1 (1.8)	19 (2.6)	20 (2.5)
Not reported	0	5 (0.7)	5 (0.6)
Unknown	0	6 (0.8)	6 (0.8)
Ethnicity			
Hispanic or Latino	10 (18.2)	177 (23.8)	187 (23.4)
Not Hispanic or Latino	45 (81.8)	563 (75.7)	608 (76.1)
Not reported	0	2 (0.3)	2 (0.3)
Unknown	0	2 (0.3)	2 (0.3)
High risk condition			
Yes	16 (29.1)	177 (23.8)	193 (24.2)
No	39 (70.9)	567 (76.2)	606 (75.8)
BMI ≥30	29 (52.7)	326 (43.8)	355 (44.4)
BMI <30	26 (47.3)	415 (55.8)	441 (55.2)

Abbreviations: BLA=biologics license application; BMI=body mass index; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set who had COVID-19 starting 14 days after dose 2; n=number participants in the subgroup.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys.

Percentages are based on the number of participants in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.

[a] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.1.3.4.4.

Table 12: (Table J) Subgroup Analysis of Final Blinded Efficacy Analysis by Risk Factor, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	**Placebo N=14164; Cases /n (%); Incidence rate per 1,000 person-years**	**Vaccine Efficacy % (95% CI)**
High risk condition			
Yes	16/3283 (0.5); 12.044	177/3212 (5.5); 141.721	0.917 (0.862, 0.950)
No	39/11004 (0.4); 8.861	567/10952 (5.2); 135.119	0.936 (0.912, 0.954)
Risk Factor			
Chronic lung disease	4/675 (0.6); 14.393	30/692 (4.3); 109.173	0.872 (0.638, 0.955)
Significant cardiac disease	4/726 (0.6); 13.666	30/696 (4.3); 110.007	0.880 (0.659, 0.958)
Severe obesity	7/1009 (0.7); 17.010	75/980 (7.7); 196.938	0.914 (0.814, 0.960)
Diabetes	3/1402 (0.2); 5.313	72/1363 (5.3); 135.672	0.962 (0.879, 0.988)
Liver disease	1/100 (1.0); 24.677	5/90 (5.6); 143.213	0.810 (-0.648, 0.978)
HIV infection	0/85; 0.000	4/82 (4.9); 145.445	1.000 (NE, 1.000)
BMI: <30 kg/m^2	26/8741 (0.3); 7.465	415/8719 (4.8); 124.605	0.942 (0.913, 0.961)
BMI: ≥ 30 kg/m^2	29/5460 (0.5); 13.102	326/5365 (6.1); 156.487	0.918 (0.881, 0.944)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; N=number of participants in per-protocol set; NE=not estimable; n=number participants in the subgroup; RT-PCR=reverse-transcription polymerase chain reaction.

Notes: Censoring rules are applied as for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.1.3.6.7.1, Table 14.2.2.1.3.6.12.1.

Table 13: (Table K) Subgroup Analysis of Final Efficacy Analysis by Baseline SARS-CoV-2 Status, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Full Analysis Set)

Baseline SARS-CoV-2	mRNA-1273 N=15180; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=15166; Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Regardless of baseline SARS-CoV-2 status	58/15180 (0.4); 9.622	754/15166 (5.0); 130.721	0.928 (0.906, 0.945)
Positive	0/347; 0.000	0/337; 0.000	NE (NE, NE)
Negative	58/14746 (0.4); 9.892	751/14745 (5.1); 133.999	0.928 (0.906, 0.945)
Missing	0/87; 0.000	3/84 (3.6); 86.723	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the full analysis set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years; Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.7.3.1, Table 14.2.2.7.3.6.10.

Table 14: (Table L) Final Blinded Efficacy Analysis of Secondary Efficacy Endpoints, COVID-19 Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA for the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 n/N (%); Incidence rate per 1,000 person-years	Placebo n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Severe COVID-19			
All participants	2/14287 (<0.1); 0.349	106/14164 (0.7); 19.112	98.2 (92.8, 99.6)
≥18 to <65 years	1/10661 (<0.1); 0.233	76/10569 (0.7); 18.351	98.7 (91.0, 99.8)
≥65 years	1/3626 (<0.1); 0.690	30/3595 (0.8); 21.358	96.9 (77.1, 99.6)
Secondary (CDC) definition of COVID-19			
All participants	58/14287 (0.4); 10.124	807/14164 (5.7); 148.525	93.4 (91.4, 94.9)
≥18 to <65 years	49/10661 (0.5); 11.446	695/10569 (6.6); 171.969	93.5 (91.3, 95.2)
≥65 years	9/3626 (0.2); 6.217	112/3595 (3.1); 80.459	92.5 (85.2, 96.2)

	mRNA-1273 n/N (%); Incidence rate per 1,000 person-years	Placebo n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
SARS-CoV-2 Infection (regardless of symptoms)			
All participants	280/14287 (2.0); 48.652	1339/14164 (9.5); 246.032	82.0 (79.5, 84.2)
≥18 to <65 years	222/10661 (2.1); 51.630	1135/10569 (10.7); 280.572	83.2 (80.6, 85.5)
≥65 years	58/3626 (1.6); 39.853	204/3595 (5.7); 146.019	75.0 (66.6, 81.4)
Deaths caused by COVID-19			
All participants	0/14287; 0	3/14164 (<0.1); 0.54	100
≥18 to <65 years	0/10661; 0	3/10569 (<0.1); 0.72	100
≥65 years	0/3626; 0	0/3595; 0	NE
Asymptomatic infection			
All participants	214/14287 (1.5); 37.178	498/14164 (3.5); 91.508	63.0 (56.6, 68.5)
≥18 to <65 years	167/10661 (1.6); 38.834	414/10569 (3.9); 102.349	65.3 (58.4, 71.0)
≥65 years	47/3626 (1.3); 32.285	84/3595 (2.3); 60.122	51.6 (30.9, 66.1)
Based on N-serology only	61/14287 (0.4); 10.60	339/14164 (2.4); 62.29	84.6 (79.7, 88.3)
Based on positive RT-PCR only	160/14287 (1.1); 27.80	272/14164 (1.9); 49.98	49.4 (38.5, 58.4)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in analysis set; NE=not estimable; RT-PCR=reverse-transcription polymerase chain reaction.

Notes: Censoring rules are applied as for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case. For asymptomatic infection, RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or secondary definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection. Person-years is defined as the total years from randomization date to the date of relevant event (severe COVID-19, COVID-19 secondary definition, SARS-CoV-2 infection, death caused by COVID-19, or asymptomatic infection), the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.1.1.1.1.1.2, Table 14.2.2.2.3.1.1, Table 14.2.2.2.3.6.1, Table 14.2.2.3.1.1.2, Table 14.2.2.4.2.1.1, Table 14.2.2.6.2.1.1.2; Ad hoc Table 14.2.2.3.6.1.1.2, Ad hoc Table 14.2.2.4.2.7.1.1, Ad hoc Table 14.2.2.6.2.6.1.1.

Table 15: (Table M) Updated Demographics Characteristics of Participants with Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

Characteristic	mRNA-1273 (N=2) n (%)	Placebo (N=106) n (%)	Total (N=108) n (%)
Sex			
Female	1 (50.0)	56 (52.8)	57 (52.8)
Male	1 (50.0)	50 (47.2)	51 (47.2)
Age			
18 to <65	1 (50.0)	76 (71.7)	77 (71.3)
65 to <75	1 (50.0)	23 (21.7)	24 (22.2)
70 to <75	1 (50.0)	10 (9.4)	11 (10.2)
75 to <80	0	5 (4.7)	5 (4.6)
≥80	0	2 (1.9)	2 (1.9)
Race			
American Indian or Alaska Native	0	0	0
Asian	0	4 (3.8)	4 (3.7)
Black or African American	0	6 (5.7)	6 (5.6)
Native Hawaiian or Other Pacific Islander	0	0	0
White	2 (100)	86 (81.1)	88 (81.5)
Multiracial	0	3 (2.8)	3 (2.8)
Other	0	4 (3.8)	4 (3.7)
Not reported	0	2 (1.9)	2 (1.9)
Unknown	0	1 (0.9)	1 (0.9)
Ethnicity			
Hispanic or Latino	1 (50.0)	21 (19.8)	22 (20.4)
Not Hispanic or Latino	1 (50.0)	84 (79.2)	85 (78.7)
Not reported	0	0	0
Unknown	0	1 (0.9)	1 (0.9)
High risk conditions			
One high risk condition present	1 (50.0)	32 (30.2)	33 (30.6)
Two or more high risk conditions present	0	12 (11.3)	12 (11.1)
No high risk condition	1 (50.0)	62 (58.5)	63 (58.3)
BMI: <30 kg/m^2	1 (50.0)	45 (42.5)	46 (42.6)
BMI: ≥30 kg/m^2	1 (50.0)	60 (56.6)	61 (56.5)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in per-protocol set who had severe COVID-19 starting 14 days after dose 2; n=number participants in the subgroup.

Notes: * with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Percentages are based on the number of participants in Per-Protocol Set with severe COVID-19 based on adjudication committee assessments starting 14 days after second injection (N).

[a] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).

Source: Ad hoc Table 14.1.3.4.5.

Table 16: (Table N) Final Blinded Subgroup Analysis of Efficacy Against Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

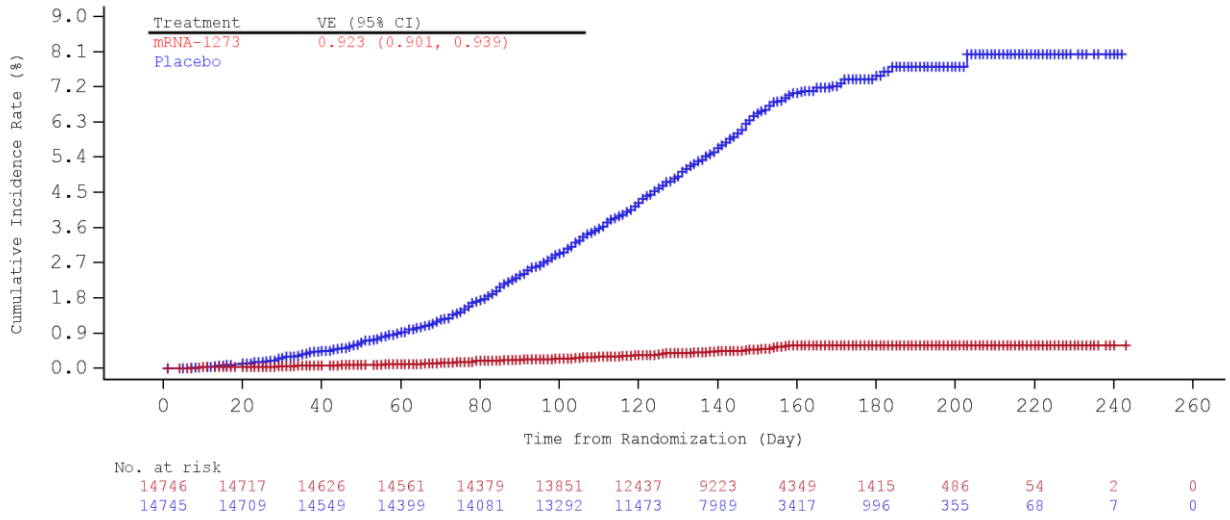
	mRNA-1273 n/N (%); Incidence rate per 1,000 person-years	Placebo n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Sex			
Female	1/6848 (<0.1); 0.363	56/6670 (0.8); 21.343	0.983 (0.880, 0.998)
Male	1/7439 (<0.1); 0.336	50/7494 (0.7); 17.109	0.981 (0.860, 0.997)
Age			
≥18 to <65 years	1/10661 (<0.1); 0.233	76/10569 (0.7); 18.351	0.987 (0.910, 0.998)
≥65 to <75 years	1/2990 (<0.1); 0.837	23/2898 (0.8); 20.282	0.960 (0.705, 0.995)
≥75 to <85 years	0/599; 0.000	6/651 (0.9); 23.741	1.000 (NE, 1.000)
≥85 years	0/37; 0.000	1/46 (2.2); 55.849	1.000 (NE, 1.000)
Race			
American Indian or Alaska Native	0/109; 0.000	0/113; 0.000	NE (NE, NE)
Asian	0/628; 0.000	4/700 (0.6); 16.064	1.000 (NE, 1.000)
Black or African American	0/1395; 0.000	6/1352 (0.4); 11.919	1.000 (NE, 1.000)
Native Hawaiian or other Pacific Islander	0/36; 0.000	0/31; 0.000	NE (NE, NE)
White	2/11391 (<0.1); 0.430	86/11273 (0.8); 19.132	0.978 (0.911, 0.995)
Multiracial	0/300; 0.000	3/304 (1.0); 27.494	1.000 (NE, 1.000)
Other	0/282; 0.000	4/274 (1.5); 41.955	1.000 (NE, 1.000)
Not reported	0/90; 0.000	2/65 (3.1); 82.945	1.000 (NE, 1.000)
Unknown	0/56; 0.000	1/52 (1.9); 58.883	1.000 (NE, 1.000)
Ethnicity			
Hispanic or Latino	1/2831 (<0.1); 0.919	21/2787 (0.8); 20.274	0.955 (0.664, 0.994)
Not Hispanic or Latino	1/11322 (<0.1); 0.218	84/11249 (0.7); 18.829	0.989 (0.919, 0.998)
Not reported	0/99; 0.000	0/76; 0.000	NE (NE, NE)
Unknown	0/35; 0.000	1/52 (1.9); 53.066	1.000 (NE, 1.000)
High risk conditions			
Yes	1/3283 (<0.1); 0.752	44/3212 (1.4); 34.638	0.979 (0.846, 0.997)
No	1/11004 (<0.1); 0.227	62/10952 (0.6); 14.500	0.985 (0.889, 0.998)
BMI: ≥40 kg/m^2	0/1009; 0.000	15/980 (1.5); 38.401	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in per-protocol set; n=number of participants in the subgroup; NE=not estimable; RT-PCR=reverse-transcription polymerase chain reaction.

Notes: Censoring rules are applied as for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate is defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years; Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.2.3.6.4, Table 14.2.2.2.3.6.5, Table 14.2.2.2.3.6.6, Table 14.2.2.2.3.6.7, Table 14.2.2.2.3.6.8.

Figure 1: Cumulative Incidence Curve of COVID-19* Cases Over Time Based on Adjudication Committee Assessments Starting 14 Days after Randomization (Vaccine vs Placebo) (Based on Data Cutoff for the BLA) (mITT Set)



Abbreviations: BLA= biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; mITT=modified intent-to-treat; RT-PCR=reverse transcriptase polymerase chain reaction; VE=vaccine efficacy.

Notes: * with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Figure 14.2.2.1.3.1.4.

Table 17: (Table O) Final Blinded Analysis of COVID-19 Cases Based on Adjudication Committee Assessments From Randomization by Time Period (Based on Data Cutoff for the BLA For the Blinded Phase) (mITT Set)

First COVID-19 occurrence	mRNA-1273 N=14746; n/N (%); Incidence rate per 1,000 person-years	Placebo N=14745; n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Any time after dose 1	69/14746 (0.5) 11.8	834/14745 (5.7) 148.8	92.1 (89.9, 93.9)
Any time after dose 1 to before dose 2	10/14746 (0.1) 8.5	59/14745 (0.4) 49.7	83.0 (66.5, 92.2)
14 days after dose 1 to before 14 days after dose 2	5/14725 (<0.1) 4.2	72/14721 (0.5) 61.0	93.0 (83.0, 97.8)
Any time after dose 2	59/14412 (0.4) 12.8	775/14317 (5.4) 177.9	92.8 (90.6, 94.6)
Dose 2 to before 14 days after dose 2	1/14412 (<0.1) 1.8	24/14317 (0.2) 43.8	95.9 (74.6, 99.9)
14 days after dose 2 to <2 months after dose 2	20/14403 (0.1) 12.1	230/14279 (1.6) 141.9	91.4 (86.5, 94.9)
2 months after dose 2 to <4 months after dose 2	30/14102 (0.2) 15.8	437/13684 (3.2) 246.5	93.6 (90.7, 95.7)
≥4 months after dose 2	8/8482 (0.1) 15.3	84/7261 (1.2) 203.0	92.5 (84.4, 96.8)
First severe COVID-19 occurrence			
Any time after dose 1	4/14746 (<0.1) 0.7	114/14745 (0.8) 19.9	96.6 (91.0, 99.1)
Any time after dose 1 to before dose 2	2/14746 (<0.1) 1.7	6/14745 (<0.1) 5.1	66.6 (-86.8, 96.7)
14 days after dose 1 to before 14 days after dose 2	2/14731 (<0.1) 1.7	7/14732 (<0.1) 5.9	71.4 (-50.2, 97.1)
Any time after dose 2	2/14412 (<0.1) 0.4	108/14320 (0.8) 24.2	98.2 (93.4, 99.8)
Dose 2 to before 14 days after dose 2	0/14412 0	1/14320 (<0.1) 1.8	100
14 days after dose 2 to <2 months after dose 2	0/14405 0	33/14306 (0.2) 20.2	100 (88.3, -)
2 months after dose 2 to <4 months after dose 2	2/14123 (<0.1) 1.0	61/13907 (0.4) 33.4	96.9 (88.2, 99.6)
≥4 months after dose 2	0/8517 0	13/7669 (0.2) 29.0	100 (72.0. -)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; mITT=modified intent-to-treat; N=number of participants in analysis set; n=number of participants in the subgroup.
Notes: Incidence rate is defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) in each treatment group within a given time period. Person-years for each time period is defined as the total years from the start of each time period to the date of COVID-19, the end of each time period, last date of study participation, efficacy data cutoff date, end date of the blinded phase, whichever is the earliest. Vaccine efficacy (VE) is defined as 1 - ratio of incidence rates (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years. 1 month = 28 days.

Table 18: (Table P) Final Blinded Analysis of All Cause Mortality From After Randomization (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287	**Placebo N=14164**	**Vaccine Efficacy % (95% CI)**
All participants, cases, n (%)	12 (<0.1)	12 (<0.1)	7.2 (-106.8, 58.3)

Abbreviations: BLA=Biologics License Application; CI=confidence interval; N= number of participants in per protocol set; n=number of participants in the subgroup.
Note: Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.2.8.1.1.

Table 19: (Table Q) Deaths From COVID-19 (Based on Data Cutoff for the BLA for the Blinded Phase) (mITT Set)

Study Arm	Participant Number	Age/Sex	Risk Factors	Date of Onset of COVID-19	Date of Death From COVID-19	Date of Dose 1	Date of Dose 2
mRNA-1273	US3702010	74/M	Liver disease, human immunodeficiency virus infection	2021-01-08	2021-02-25	2020-09-04	Not received[a]
Placebo	US3032204	54/M	Diabetes	2020-11-11	2020-11-16	2020-08-14	2020-09-14
Placebo[b]	US3572086	63/M	Significant cardiac disease	2021-01-03	2021-02-12	2020-08-25	2020-09-23
Placebo	US3952094	57/M	Diabetes	2020-12-24	2021-01-30	2020-09-15	2020-10-14

Abbreviations: BLA= biologics license application; COVID-19= coronavirus disease 2019; M=male; mITT=modified intent-to-treat.

[a] The participant is noted as having "refused second injection due to side effects however, consented to continue study visits" (Listing 16.2.1.1). No adverse events were reported as leading to discontinuation of vaccine, but events that occurred within 8 days of Day 1 were severe nausea and severe fatigue that were considered related to treatment (P301 Clinical Study Report).

[b] This was not COVID-19 based on adjudication committee assessments.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Listing 16.2.6.2.5, Listing 16.2.12.

Table 20: (Table R) Participants with Multiple, Separate, Symptomatic Confirmed COVID-19 (Based on Data Cutoff for the BLA for the Blinded Phase) (miTT Set)

Study Arm	Participant Number	COVID-19 Episode 1		COVID-19 Episode 2		Date of Dose 1	Date of Dose 2
		Onset date	Further Information	Onset date	Further Information		
mRNA-1273	US3812263	12 Nov 2020	None	10 Dec 2020	None	26 Aug 2020	23 Sep 2020
Placebo	US3932083	16 Nov 2020	Severe	14 Dec 2020	Severe	10 Sep 2020	08 Oct 2020
Placebo	US3142100	21 Sep 2020	Severe	20 Oct 2020	Severe	04 Aug 2020	03 Sep 2020
Placebo	US3262099	12 Oct 2020	None	09 Nov 2020	None	05 Aug 2020	03 Sep 2020
Placebo	US3442051	25 Oct 2020	None	11 Jan 2021	Severe	20 Aug 2020	17 Sep 2020

Abbreviations: BLA=biologics license application; COVID-19=coronavirus disease 2019; mITT=modified intent-to-treat; NA=not applicable; RT-PCR=reverse-transcription polymerase chain reaction.

Note: COVID-19 diagnosis based on positive RT-PCR and eligible symptoms. COVID-19 cases presented in this table occurred during the blinded phase. A separate occurrence of symptomatic COVID-19 is identified by the onset date of symptomatic COVID-19 at least 28 days after the onset date of the previous occurrence of symptomatic COVID-19.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Listing 16.2.6.2.5.

Table 21: (Table S) Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for First COVID-19 Occurrence from 14 Days After Dose 2 in Cases that were Sequenced (Based on Data Cutoff for the BLA for the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287 n (%)	Placebo N=14164 n (%)	Total N=28451 n (%)
Confirmed cases that were sequenced	56 (0.4)	769 (5.4)	825 (2.9)
In sequenced cases, SARS-CoV-2 lineage identified			
B.1	0	5 (<0.1)	5 (<0.1)
B.1.1	0	1 (<0.1)	1 (<0.1)
B.1.1.128	0	1 (<0.1)	1 (<0.1)
B.1.1.186	0	2 (<0.1)	2 (<0.1)
B.1.1.207	0	1 (<0.1)	1 (<0.1)
B.1.1.222	0	8 (<0.1)	8 (<0.1)
B.1.1.316	0	1 (<0.1)	1 (<0.1)
B.1.1.337	0	1 (<0.1)	1 (<0.1)
B.1.1.432	0	1 (<0.1)	1 (<0.1)
B.1.1.434	0	1 (<0.1)	1 (<0.1)
B.1.1.519	0	2 (<0.1)	2 (<0.1)
B.1.2	13 (<0.1)	394 (2.8)	407 (1.4)
B.1.232	0	1 (<0.1)	1 (<0.1)
B.1.234	0	6 (<0.1)	6 (<0.1)
B.1.240	0	1 (<0.1)	1 (<0.1)
B.1.243	1 (<0.1)	23 (0.2)	24 (<0.1)
B.1.311	0	6 (<0.1)	6 (<0.1)
B.1.349	0	1 (<0.1)	1 (<0.1)
B.1.369	0	2 (<0.1)	2 (<0.1)
B.1.375	0	1 (<0.1)	1 (<0.1)
B.1.382	0	1 (<0.1)	1 (<0.1)
B.1.396	0	1 (<0.1)	1 (<0.1)
B.1.404	0	2 (<0.1)	2 (<0.1)
B.1.427	0	6 (<0.1)	6 (<0.1)
B.1.429	3 (<0.1)	9 (<0.1)	12 (<0.1)
B.1.517	0	2 (<0.1)	2 (<0.1)
B.1.526.3	0	1 (<0.1)	1 (<0.1)
B.1.544	0	2 (<0.1)	2 (<0.1)
B.1.551	0	1 (<0.1)	1 (<0.1)
B.1.561	0	5 (<0.1)	5 (<0.1)
B.1.564	0	3 (<0.1)	3 (<0.1)
B.1.587	0	8 (<0.1)	8 (<0.1)
B.1.595	0	2 (<0.1)	2 (<0.1)
B.1.596	0	13 (<0.1)	13 (<0.1)
B.1.599	0	1 (<0.1)	1 (<0.1)
B.1.605	0	1 (<0.1)	1 (<0.1)
B.1.609	0	1 (<0.1)	1 (<0.1)
NONE	0	20 (0.1)	20 (<0.1)

	mRNA-1273 N=14287 n (%)	**Placebo N=14164 n (%)**	**Total N=28451 n (%)**
P.1	0	1 (<0.1)	1 (<0.1)
P.2	0	2 (<0.1)	2 (<0.1)
R.1	0	3 (<0.1)	3 (<0.1)
WILD TYPE	0	1 (<0.1)	1 (<0.1)
By first detected			
Brazil	0	1 (<0.1)	1 (<0.1)
P.1	0	1 (<0.1)	1 (<0.1)
California	3 (<0.1)	15 (0.1)	18 (<0.1)
B.1.427	0	6 (<0.1)	6 (<0.1)
B.1.429	3 (<0.1)	9 (<0.1)	12 (<0.1)
Variant of concern			
B.1.427[a]	0	6 (<0.1)	6 (<0.1)
B.1.429[a]	3 (<0.1)	9 (<0.1)	12 (<0.1)
P.1	0	1 (<0.1)	1 (<0.1)
Variant of interest			
P.2	0	2 (<0.1)	2 (<0.1)

Abbreviations: BLA=Biologics Licensing Application; COVID-19=coronavirus disease 2019; QNS=quantity not sufficient; RT-PCR=reverse-transcription polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Note: Percentages are based on the number of participants in the per-protocol set. Censoring rules were applied as for the efficacy analyses. A COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had a positive RT-PCR test at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant was censored at the date with positive RT-PCR or Elecsys.

[a] Considered variants of interest by the Centers for Disease Control and Prevention at the time of clinical study report finalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.2.1.1.2.1.4.1.

5 Safety Analysis

5.1 Overall Safety

Table 22: (Table T) Safety Overview (Safety Set and Solicited Safety Set)

Participants reporting at least one	**mRNA-1273**	**Placebo**
Solicited AR within 30 minutes after vaccination	**n/N (%)**	**n/N (%)**
Dose 1	74/15184 (0.5)	68/15162 (0.4)
Dose 2	47/14631 (0.3)	41/14631 (0.3)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	12765/15162 (84.2)	3009/15147 (19.9)
Dose 2	13029/14688 (88.7)	2757/14577 (18.9)
Grade 3 or 4 solicited local AR (any dose)	1420/15179 (9.4)	148/15158 (1.0)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	8316/15166 (54.8)	6397/15151 (42.2)
Dose 2	11678/14690 (79.5)	5343/14577 (36.7)
Grade 3 or 4 systemic AR (any dose)	2640/15178 (17.4)	571/15159 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	4752/15184 (31.3)	4338/15162 (28.6)
Non-serious unsolicited AE	4716/15184 (31.1)	4294/15162 (28.3)
Related non-serious unsolicited AE	2062/15184 (13.6)	1234/15162 (8.1)
Severe non-serious unsolicited AE	225/15184 (1.5)	186/15162 (1.2)
Related severe non-serious unsolicited AE	82/15184 (0.5)	30/15162 (0.2)
MAAE up to 28 days after any injection	1819/15184 (12.0)	1940/15162 (12.8)
Related MAAE	198/15184 (1.3)	95/15162 (0.6)
SAE	98/15184 (0.6)	104/15162 (0.7)
Related SAE	8/15184 (<0.1)	3/15162 (<0.1)
Deaths up to 28 days after any injection	2/15184 (<0.1)	2/15162 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	61/15184 (0.4)	92/15162 (0.6)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse events; SAE=serious adverse event; TEAE=treatment-emergent adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.3.1.1.1.3, Table 14.3.1.7.1.1, Table 14.3.1.19.5.1, Table 14.3.1.19.5.2, Table 14.3.1.23.1.1.

Table 23: (Table T) Safety Overview, by Baseline SARS-CoV-2 Status (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
Baseline SARS-CoV-2 Status Positive		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	27/346 (7.8)	27/337 (8.0)
Dose 2	15/232 (6.5)	22/233 (9.4)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	250/346 (72.3)	60/337 (17.8)
Dose 2	172/232 (74.1)	42/232 (18.1)
Grade 3 or 4 solicited local AR (any dose)	23/347 (6.6)	5/337 (1.5)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	214/346 (61.8)	122/337 (36.2)
Dose 2	152/232 (65.5)	73/233 (31.3)
Grade 3 or 4 systemic AR (any dose)	38/347 (11.0)	13/337 (3.9)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	77/347 (22.2)	92/337 (27.3)
Non-serious unsolicited AE	76/347 (21.9)	92/337 (27.3)
Related non-serious unsolicited AE	30/347 (8.6)	30/337 (8.9)
Severe non-serious unsolicited AE	1/347 (0.3)	5/337 (1.5)
Related severe non-serious unsolicited AE	0	1/337 (0.3)
MAAE up to 28 days after any injection	25/347 (7.2)	35/337 (10.4)
Related MAAE	1/347 (0.3)	5/337 (1.5)
SAE up to 28 days after any injection	1/347 (0.3)	3/337 (0.9)
Related SAE	0	0
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	6/347 (1.7)	8/337 (2.4)
Baseline SARS-CoV-2 Status Negative		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1538/14733 (10.4)	1558/14730 (10.6)
Dose 2	1435/14378 (10.0)	1535/14267 (10.8)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	12442/14729 (84.5)	2934/14726 (19.9)
Dose 2	12783/14375 (88.9)	2699/14267 (18.9)
Grade 3 or 4 solicited local AR (any dose)	1385/14745 (9.4)	143/14737 (1.0)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	8053/14733 (54.7)	6239/14730 (42.4)
Dose 2	11459/14377 (79.9)	5241/14266 (36.7)
Grade 3 or 4 systemic AR (any dose)	2590/14744 (17.6)	557/14738 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	4652/14750 (31.5)	4233/14741 (28.7)
Non-serious unsolicited AE	4617/14750 (31.3)	4189/14741 (28.4)
Related non-serious unsolicited AE	2027/14750 (13.7)	1199/14741 (8.1)
Severe non-serious unsolicited AE	224/14750 (1.5)	180/14741 (1.2)
Related severe non-serious unsolicited AE	82/14750 (0.6)	29/14741 (0.2)

MAAE up to 28 days after any injection	1782/14750 (12.1)	1902/14741 (12.9)
Related MAAE	197/14750 (1.3)	90/14741 (0.6)
SAE up to 28 days after any injection	96/14750 (0.7)	101/14741 (0.7)
Related SAE	8/14750 (<0.1)	3/14741 (<0.1)
Deaths up to 28 days after any injection	2/14750 (<0.1)	2/14741 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	54/14750 (0.4)	84/14741 (0.6)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2, Table 14.3.1.1.3.3, Table 14.3.1.7.3.1, Table 14.3.1.3.3.1, Table 14.3.1.3.3.2; Ad hoc Table 14.3.1.23.9.1.

Table 24: (Table T) Safety Overview, by Race (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
White		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1235/12020 (10.3)	1270/11993 (10.6)
Dose 2	1130/11677 (9.7)	1225/11572 (10.6)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	10247/12018 (85.3)	2410/11991 (20.1)
Dose 2	10510/11674 (90.0)	2215/11571 (19.1)
Grade 3 or 4 solicited local AR (any dose)	1127/12030 (9.4)	113/11995 (0.9)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6567/12020 (54.6)	5117/11993 (42.7)
Dose 2	9404/11676 (80.5)	4307/11572 (37.2)
Grade 3 or 4 systemic AR (any dose)	2117/12029 (17.6)	450/11996 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	3674/12034 (30.5)	3326/11998 (27.7)
Non-serious unsolicited AE	3648/12034 (30.3)	3292/11998 (27.4)
Related non-serious unsolicited AE	1582/12034 (13.1)	956/11998 (8.0)
Severe non-serious unsolicited AE	168/12034 (1.4)	133/11998 (1.1)
Related severe non-serious unsolicited AE	67/12034 (0.6)	25/11998 (0.2)
MAAE up to 28 days after any injection	1446/12034 (12.0)	1548/11998 (12.9)
Related MAAE	147/12034 (1.2)	72/11998 (0.6)
SAE up to 28 days after any injection	75/12034 (0.6)	80/11998 (0.7)
Related SAE	5/12034 (<0.1)	1/11998 (<0.1)
Deaths up to 28 days after any injection	2/12034 (<0.1)	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	43/12034 (0.4)	70/11998 (0.6)
Black or African American		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	147/1564 (9.4)	122/1527 (8.0)
Dose 2	140/1470 (9.5)	132/1432 (9.2)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1107/1564 (70.8)	249/1526 (16.3)
Dose 2	1094/1470 (74.4)	215/1432 (15.0)
Grade 3 or 4 solicited local AR (any dose)	109/1566 (7.0)	23/1530 (1.5)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	785/1564 (50.2)	574/1527 (37.6)
Dose 2	938/1470 (63.8)	459/1432 (32.1)
Grade 3 or 4 systemic AR (any dose)	172/1566 (11.0)	65/1530 (4.2)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	484/1567 (30.9)	465/1531 (30.4)
Non-serious unsolicited AE	477/1567 (30.4)	458/1531 (29.9)
Related non-serious unsolicited AE	196/1567 (12.5)	132/1531 (8.6)
Severe non-serious unsolicited AE	29/1567 (1.9)	28/1531 (1.8)
Related severe non-serious unsolicited AE	6/1567 (0.4)	4/1531 (0.3)
MAAE up to 28 days after any injection	174/1567 (11.1)	184/1531 (12.0)
Related MAAE	15/1567 (1.0)	14/1531 (0.9)

SAE up to 28 days after any injection	12/1567 (0.8)	15/1531 (1.0)
Related SAE	0	0
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	10/1567 (0.6)	10/1531 (0.7)
Asian		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	79/656 (12.0)	84/737 (11.4)
Dose 2	71/641 (11.1)	92/718 (12.8)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	590/655 (90.1)	154/736 (20.9)
Dose 2	599/641 (93.4)	141/718 (19.6)
Grade 3 or 4 solicited local AR (any dose)	89/656 (13.6)	4/739 (0.5)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	392/656 (59.8)	283/737 (38.4)
Dose 2	574/641 (89.5)	236/717 (32.9)
Grade 3 or 4 systemic AR (any dose)	148/656 (22.6)	19/739 (2.6)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	218/656 (33.2)	188/739 (25.4)
Non-serious unsolicited AE	217/656 (33.1)	188/739 (25.4)
Related non-serious unsolicited AE	110/656 (16.8)	39/739 (5.3)
Severe non-serious unsolicited AE	11/656 (1.7)	5/739 (0.7)
Related severe non-serious unsolicited AE	4/656 (0.6)	0
MAAE up to 28 days after any injection	74/656 (11.3)	65/739 (8.8)
Related MAAE	14/656 (2.1)	1/739 (0.1)
SAE up to 28 days after any injection	3/656 (0.5)	1/739 (0.1)
Related SAE	3/656 (0.5)	0
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	4/656 (0.6)	1/739 (0.1)
American Indian or Alaska Native		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	17/113 (15.0)	16/121 (13.2)
Dose 2	7/110 (6.4)	14/115 (12.2)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	99/113 (87.6)	20/121 (16.5)
Dose 2	101/110 (91.8)	22/115 (19.1)
Grade 3 or 4 solicited local AR (any dose)	9/113 (8.0)	2/121 (1.7)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	75/113 (66.4)	48/121 (39.7)
Dose 2	90/110 (81.8)	44/115 (38.3)
Grade 3 or 4 systemic AR (any dose)	22/113 (19.5)	4/121 (3.3)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	47/113 (41.6)	39/121 (32.2)
Non-serious unsolicited AE	47/113 (41.6)	39/121 (32.2)
Related non-serious unsolicited AE	16/113 (14.2)	11/121 (9.1)
Severe non-serious unsolicited AE	2/113 (1.8)	1/121 (0.8)
Related severe non-serious unsolicited AE	0	0

MAAE up to 28 days after any injection	21/113 (18.6)	21/121 (17.4)
Related MAAE	1/113 (0.9)	0
SAE up to 28 days after any injection	0	1/121 (0.8)
Related SAE	0	0
Deaths up to 28 days after any injection	0	1/121 (0.8)
AE leading to discontinuation of the vaccine up to 28 days after any injection	0	0
Native Hawaiian or Other Pacific Islander		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	2/36 (5.6)	2/32 (6.3)
Dose 2	5/36 (13.9)	3/31 (9.7)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	32/36 (88.9)	7/32 (21.9)
Dose 2	33/36 (91.7)	5/31 (16.1)
Grade 3 or 4 solicited local AR (any dose)	4/36 (11.1)	2/32 (6.3)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	15/36 (41.7)	16/32 (50.0)
Dose 2	30/36 (83.3)	16/31 (51.6)
Grade 3 or 4 systemic AR (any dose)	4/36 (11.1)	0
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	8/36 (22.2)	9/32 (28.1)
Non-serious unsolicited AE	8/36 (22.2)	9/32 (28.1)
Related non-serious unsolicited AE	3/36 (8.3)	2/32 (6.3)
Severe non-serious unsolicited AE	0	0
Related severe non-serious unsolicited AE	0	0
MAAE up to 28 days after any injection	2/36 (5.6)	5/32 (15.6)
Related MAAE	0	0
SAE up to 28 days after any injection	0	0
Related SAE	0	0
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	0	0
Multiple		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	45/320 (14.1)	40/318 (12.6)
Dose 2	56/314 (17.8)	50/307 (16.3)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	298/319 (93.4)	69/318 (21.7)
Dose 2	296/314 (94.3)	81/307 (26.4)
Grade 3 or 4 solicited local AR (any dose)	34/320 (10.6)	1/318 (0.3)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	205/320 (64.1)	153/318 (48.1)
Dose 2	271/314 (86.3)	122/307 (39.7)
Grade 3 or 4 systemic AR (any dose)	77/320 (24.1)	16/318 (5.0)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	132/320 (41.3)	129/318 (40.6)
Non-serious unsolicited AE	132/320 (41.3)	127/318 (39.9)
Related non-serious unsolicited AE	65/320 (20.3)	43/318 (13.5)

Severe non-serious unsolicited AE	6/320 (1.9)	5/318 (1.6)
Related severe non-serious unsolicited AE	1/320 (0.3)	0
MAAE up to 28 days after any injection	51/320 (15.9)	53/318 (16.7)
Related MAAE	12/320 (3.8)	4/318 (1.3)
SAE up to 28 days after any injection	4/320 (1.3)	3/318 (0.9)
Related SAE	0	0
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	1/320 (0.3)	4/318 (1.3)
Other/Not Reported/Unknown		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	47/457 (10.3)	62/423 (14.7)
Dose 2	51/443 (11.5)	51/403 (12.7)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	392/457 (85.8)	100/423 (23.6)
Dose 2	396/443 (89.4)	78/403 (19.4)
Grade 3 or 4 solicited local AR (any dose)	48/458 (10.5)	3/423 (0.7)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	277/457 (60.6)	206/423 (48.7)
Dose 2	371/443 (83.7)	159/403 (39.5)
Grade 3 or 4 systemic AR (any dose)	100/458 (21.8)	17/423 (4.0)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	189/458 (41.3)	182/423 (43.0)
Non-serious unsolicited AE	187/458 (40.8)	181/423 (42.8)
Related non-serious unsolicited AE	90/458 (19.7)	51/423 (12.1)
Severe non-serious unsolicited AE	9/458 (2.0)	13/423 (3.1)
Related severe non-serious unsolicited AE	4/458 (0.9)	1/423 (0.2)
MAAE up to 28 days after any injection	51/458 (11.1)	64/423 (15.1)
Related MAAE	9/458 (2.0)	4/423 (0.9)
SAE up to 28 days after any injection	4/458 (0.9)	4/423 (0.9)
Related SAE	0	2/423 (0.5)
Deaths up to 28 days after any injection	0	1/423 (0.2)
AE leading to discontinuation of the vaccine up to 28 days after any injection	3/458 (0.7)	7/423 (1.7)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.4.1, Table 14.3.1.1.4.2, Table 14.3.1.1.4.3, Table 14.3.1.7.4.1; Ad hoc Table 14.3.1.3.3.4.1, Ad hoc Table 14.3.1.3.3.4.2, Ad hoc Table 14.3.1.23.9.3.

Table 25: (Table T) Safety Overview, by Ethnicity (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
Hispanic or Latino		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	332/3119 (10.6)	325/3106 (10.5)
Dose 2	325/2958 (11.0)	326/2905 (11.2)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	2574/3119 (82.5)	626/3106 (20.2)
Dose 2	2557/2957 (86.5)	571/2904 (19.7)
Grade 3 or 4 solicited local AR (any dose)	285/3122 (9.1)	34/3107 (1.1)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1727/3119 (55.4)	1327/3106 (42.7)
Dose 2	2351/2957 (79.5)	1086/2905 (37.4)
Grade 3 or 4 systemic AR (any dose)	579/3121 (18.6)	104/3107 (3.3)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	1029/3122 (33.0)	1005/3108 (32.3)
Non-serious unsolicited AE	1025/3122 (32.8)	1002/3108 (32.2)
Related non-serious unsolicited AE	450/3122 (14.4)	304/3108 (9.8)
Severe non-serious unsolicited AE	33/3122 (1.1)	41/3108 (1.3)
Related severe non-serious unsolicited AE	11/3122 (0.4)	4/3108 (0.1)
MAAE up to 28 days after any injection	364/3122 (11.7)	417/3108 (13.4)
Related MAAE	43/3122 (1.4)	29/3108 (0.9)
SAE up to 28 days after any injection	12/3122 (0.4)	17/3108 (0.5)
Related SAE	0	2/3108 (<0.1)
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	16/3122 (0.5)	22/3108 (0.7)
Not Hispanic or Latino		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1229/11905 (10.3)	1253/11909 (10.5)
Dose 2	1117/11596 (9.6)	1227/11541 (10.6)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	10071/11901 (84.6)	2354/11905 (19.8)
Dose 2	10351/11594 (89.3)	2161/11541 (18.7)
Grade 3 or 4 solicited local AR (any dose)	1124/11915 (9.4)	113/11915 (0.9)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6502/11905 (54.6)	5009/11909 (42.1)
Dose 2	9219/11596 (79.5)	4209/11540 (36.5)
Grade 3 or 4 systemic AR (any dose)	2044/11915 (17.2)	464/11916 (3.9)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	3679/11920 (30.9)	3295/11918 (27.6)
Non-serious unsolicited AE	3647/11920 (30.6)	3255/11918 (27.3)
Related non-serious unsolicited AE	1593/11920 (13.4)	923/11918 (7.7)
Severe non-serious unsolicited AE	191/11920 (1.6)	143/11918 (1.2)
Related severe non-serious unsolicited AE	71/11920 (0.6)	26/11918 (0.2)
MAAE up to 28 days after any injection	1439/11920 (12.1)	1506/11918 (12.6)
Related MAAE	154/11920 (1.3)	66/11918 (0.6)

SAE up to 28 days after any injection	86/11920 (0.7)	85/11918 (0.7)
Related SAE	8/11920 (<0.1)	1/11918 (<0.1)
Deaths up to 28 days after any injection	2/11920 (<0.1)	2/11918 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	44/11920 (0.4)	6/11918 (<0.1)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.5.1, Table 14.3.1.1.5.2, Table 14.3.1.1.5.3, Table 14.3.1.7.5.1; Ad hoc Table 14.3.1.3.3.5.1, Ad hoc Table 14.3.1.3.3.5.2, Ad hoc Table 14.3.1.23.9.4.

Table 26: (Table T) Safety Overview, by Sex (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
Male		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	679/7906 (8.6)	725/8050 (9.0)
Dose 2	652/7646 (8.5)	717/7731 (9.3)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6446/7905 (81.5)	1481/8047 (18.4)
Dose 2	6606/7646 (86.4)	1320/7731 (17.1)
Grade 3 or 4 solicited local AR (any dose)	549/7914 (6.9)	79/8054 (1.0)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	4010/7906 (50.7)	3153/8050 (39.2)
Dose 2	5804/7645 (75.9)	2482/7730 (32.1)
Grade 3 or 4 systemic AR (any dose)	1026/7913 (13.0)	217/8055 (2.7)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	2173/7918 (27.4)	2092/8056 (26.0)
Non-serious unsolicited AE	2151/7918 (27.2)	2067/8056 (25.7)
Related non-serious unsolicited AE	841/7918 (10.6)	565/8056 (7.0)
Severe non-serious unsolicited AE	105/7918 (1.3)	81/8056 (1.0)
Related severe non-serious unsolicited AE	34/7918 (0.4)	12/8056 (0.1)
MAAE up to 28 days after any injection	820/7918 (10.4)	895/8056 (11.1)
Related MAAE	78/7918 (1.0)	44/8056 (0.5)
SAE up to 28 days after any injection	51/7918 (0.6)	49/8056 (0.6)
Related SAE	2/7918 (<0.1)	2/8056 (<0.1)
Deaths up to 28 days after any injection	2/7918 (<0.1)	2/8056 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	29/7918 (0.4)	45/8056 (0.6)
Female		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	893/7260 (12.3)	871/7101 (12.3)
Dose 2	808/7045 (11.5)	850/6847 (12.4)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6319/7257 (87.1)	1528/7100 (21.5)
Dose 2	6423/7042 (91.2)	1437/6846 (21.0)
Grade 3 or 4 solicited local AR (any dose)	871/7265 (12.0)	69/7104 (1.0)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	4306/7260 (59.3)	3244/7101 (45.7)
Dose 2	5874/7045 (83.4)	2861/6847 (41.8)
Grade 3 or 4 systemic AR (any dose)	1614/7265 (22.2)	354/7104 (5.0)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	2579/7266 (35.5)	2246/7106 (31.6)
Non-serious unsolicited AE	2565/7266 (35.3)	2227/7106 (31.3)
Related non-serious unsolicited AE	1221/7266 (16.8)	669/7106 (9.4)
Severe non-serious unsolicited AE	120/7266 (1.7)	105/7106 (1.5)
Related severe non-serious unsolicited AE	48/7266 (0.7)	18/7106 (0.3)
MAAE up to 28 days after any injection	999/7266 (13.7)	1045/7106 (14.7)
Related MAAE	120/7266 (1.7)	51/7106 (0.7)

SAE up to 28 days after any injection	47/7266 (0.6)	55/7106 (0.8)
Related SAE	6/7266 (<0.1)	1/7106 (<0.1)
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	32/7266 (0.4)	47/7106 (0.7)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.7.1, Table 14.3.1.1.7.2, Table 14.3.1.1.7.3, Table 14.3.1.7.7.1; Ad hoc Table 14.3.1.3.3.6.1, Ad hoc Table 14.3.1.3.3.6.2, Ad hoc Table 14.3.1.23.9.5.

Table 27: (Table T) Safety Overview, by Presence of High Risk Condition (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
At Risk		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	331/3439 (9.6)	348/3454 (10.1)
Dose 2	322/3362 (9.6)	323/3323 (9.7)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	2723/3438 (79.2)	700/3452 (20.3)
Dose 2	2852/3360 (84.9)	622/3323 (18.7)
Grade 3 or 4 solicited local AR (any dose)	295/3445 (8.6)	50/3456 (1.4)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1900/3439 (55.2)	1470/3454 (42.6)
Dose 2	2416/3361 (71.9)	1262/3323 (38.0)
Grade 3 or 4 systemic AR (any dose)	530/3444 (15.4)	132/3456 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	1188/3448 (34.5)	1073/3457 (31.0)
Non-serious unsolicited AE	1170/3448 (33.9)	1053/3457 (30.5)
Related non-serious unsolicited AE	521/3448 (15.1)	325/3457 (9.4)
Severe non-serious unsolicited AE	46/3448 (1.3)	65/3457 (1.9)
Related severe non-serious unsolicited AE	19/3448 (0.6)	13/3457 (0.4)
MAAE up to 28 days after any injection	494/3448 (14.3)	516/3457 (14.9)
Related MAAE	61/3448 (1.8)	21/3457 (0.6)
SAE up to 28 days after any injection	36/3448 (1.0)	49/3457 (1.4)
Related SAE	2/3448 (<0.1)	2/3457 (<0.1)
Deaths up to 28 days after any injection	0	0
AE leading to discontinuation of the vaccine up to 28 days after any injection	14/3448 (0.4)	27/3457 (0.8)
Not at Risk		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1241/11727 (10.6)	1248/11697 (10.7)
Dose 2	1138/11329 (10.0)	1244/11255 (11.1)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	10042/11724 (85.7)	2309/11695 (19.7)
Dose 2	10177/11328 (89.8)	2135/11254 (19.0)
Grade 3 or 4 solicited local AR (any dose)	1125/11734 (9.6)	98/11702 (0.8)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6416/11727 (54.7)	4927/11697 (42.1)
Dose 2	9262/11329 (81.8)	4081/11254 (36.3)
Grade 3 or 4 systemic AR (any dose)	2110/11734 (18.0)	439/11703 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	3564/11736 (30.4)	3265/11705 (27.9)
Non-serious unsolicited AE	3546/11736 (30.2)	3241/11705 (27.7)
Related non-serious unsolicited AE	1541/11736 (13.1)	909/11705 (7.8)
Severe non-serious unsolicited AE	179/11736 (1.5)	121/11705 (1.0)
Related severe non-serious unsolicited AE	63/11736 (0.5)	17/11705 (0.1)

MAAE up to 28 days after any injection	1325/11736 (11.3)	1424/11705 (12.2)
Related MAAE	137/11736 (1.2)	74/11705 (0.6)
SAE up to 28 days after any injection	62/11736 (0.5)	55/11705 (0.5)
Related SAE	6/11736 (<0.1)	1/11705 (<0.1)
Deaths up to 28 days after any injection	2/11736 (<0.1)	2/11705 (<0.2)
AE leading to discontinuation of the vaccine up to 28 days after any injection	47/11736 (0.4)	65/11705 (0.6)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.6.1.1, Table 14.3.1.1.6.1.2, Table 14.3.1.1.6.2.3, Table 14.3.1.7.6.2.1; Ad hoc Table 14.3.1.3.3.7.1, Ad hoc Table 14.3.1.3.3.7.2, Ad hoc Table 14.3.1.23.9.6.

Table 28: (Table T) Safety Overview, by Age Group (Safety Set and Solicited Safety Set)

Subjects reporting at least one	**mRNA-1273**	**Placebo**
Age ≥18 to <65		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1332/11406 (11.7)	1341/11402 (11.8)
Dose 2	1222/11000 (11.1)	1325/10929 (12.1)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	9961/11402 (87.4)	2436/11400 (21.4)
Dose 2	9936/10999 (90.3)	2262/10928 (20.7)
Grade 3 or 4 solicited local AR (any dose)	1133/11413 (9.9)	80/11407 (0.7)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	6499/11406 (57.0)	5063/11402 (44.4)
Dose 2	9023/10999 (82.0)	4208/10928 (38.5)
Grade 3 or 4 systemic AR (any dose)	2185/11412 (19.1)	451/11408 (4.0)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	3515/11415 (30.8)	3275/11411 (28.7)
Non-serious unsolicited AE	3489/11415 (30.6)	3252/11411 (28.5)
Related non-serious unsolicited AE	1575/11415 (13.8)	944/11411 (8.3)
Severe non-serious unsolicited AE	157/11415 (1.4)	125/11411 (1.1)
Related severe non-serious unsolicited AE	58/11415 (0.5)	20/11411 (0.2)
MAAE up to 28 days after any injection	1311/11415 (11.5)	1419/11411 (12.4)
Related MAAE	161/11415 (1.4)	78/11411 (0.7)
SAE up to 28 days after any injection	59/11415 (0.5)	54/11411 (0.5)
Related SAE	6/11415 (<0.1)	2/11411 (<0.1)
Deaths up to 28 days after any injection	1/11415 (<0.1)	1/11411 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	49/11415 (0.4)	70/11411 (0.6)
Age ≥ 65		
Solicited AR within 30 minutes after vaccination	**n/N1 (%)**	**n/N1 (%)**
Dose 1	240/3760 (6.4)	255/3749 (6.8)
Dose 2	238/3691 (6.4)	242/3649 (6.6)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	2804/3760 (74.6)	573/3747 (15.3)
Dose 2	3093/3689 (83.8)	495/3649 (13.6)
Grade 3 or 4 solicited local AR (any dose)	287/3766 (7.6)	68/3751 (1.8)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	1817/3760 (48.3)	1334/3749 (35.6)
Dose 2	2655/3691 (71.9)	1135/3649 (31.1)
Grade 3 or 4 systemic AR (any dose)	455/3766 (12.1)	120/3751 (3.2)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	1237/3769 (32.8)	1063/3751 (28.3)
Non-serious unsolicited AE	1227/3769 (32.6)	1042/3751 (27.8)
Related non-serious unsolicited AE	487/3769 (12.9)	290/3751 (7.7)
Severe non-serious unsolicited AE	68/3769 (1.8)	61/3751 (1.6)
Related severe non-serious unsolicited AE	24/3769 (0.6)	10/3751 (0.3)
MAAE up to 28 days after any injection	508/3769 (13.5)	521/3751 (13.9)
Related MAAE	37/3769 (1.0)	17/3751 (0.5)

SAE up to 28 days after any injection	39/3769 (1.0)	50/3751 (1.3)
Related SAE	2/3769 (<0.1)	1/3751 (<0.1)
Deaths up to 28 days after any injection	1/3769 (<0.1)	1/3751 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	12/3769 (0.3)	22/3751 (0.6)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse event; SAE=serious adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2, Table 14.2.1.1.2.1.3, Table 14.3.1.7.2.1.1, Table 14.3.1.3.2.1, Table 14.3.1.3.2.2; Ad hoc Table 14.3.1.23.9.2.

5.2 Solicited Adverse Reactions

5.2.1 Local Adverse Reactions

5.2.1.1 Onset Within 7 Days

Table 29: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 N=15166 n (%)	Placebo Dose 1 N=15151 n (%)	mRNA-1273 Dose 2 N=14691 n (%)	Placebo Dose 2 N=14578 n (%)
Any local AR	N1=15162	N1=15147	N1=14688	N1=14577
Any	12765 (84.2)	3009 (19.9)	13029 (88.7)	2757 (18.9)
Grade 1	10725 (70.7)	2842 (18.8)	8789 (59.8)	2594 (17.8)
Grade 2	1511 (10.0)	89 (0.6)	3217 (21.9)	88 (0.6)
Grade 3	529 (3.5)	78 (0.5)	1023 (7.0)	75 (0.5)
Grade 4	0	0	0	0
Pain	N1=15162	N1=15147	N1=14688	N1=14577
Any	12688 (83.7)	2665 (17.6)	12964 (88.3)	2486 (17.1)
Grade 1	10985 (72.5)	2551 (16.8)	9508 (64.7)	2384 (16.4)
Grade 2	1287 (8.5)	59 (0.4)	2850 (19.4)	61 (0.4)
Grade 3[a]	416 (2.7)	55 (0.4)	606 (4.1)	41 (0.3)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=15162	N1=15147	N1=14687	N1=14577
Any	445 (2.9)	77 (0.5)	1274 (8.7)	68 (0.5)
Grade 1	281 (1.9)	57 (0.4)	456 (3.1)	48 (0.3)
Grade 2	122 (0.8)	7 (<0.1)	531 (3.6)	5 (<0.1)
Grade 3	42 (0.3)	13 (<0.1)	287 (2.0)	15 (0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=15162	N1=15147	N1=14687	N1=14577
Any	935 (6.2)	65 (0.4)	1807 (12.3)	60 (0.4)
Grade 1	608 (4.0)	50 (0.3)	900 (6.1)	38 (0.3)
Grade 2	245 (1.6)	9 (<0.1)	652 (4.4)	10 (<0.1)
Grade 3[c]	82 (0.5)	6 (<0.1)	255 (1.7)	12 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=15162	N1=15147	N1=14687	N1=14577
Any	1553 (10.2)	722 (4.8)	2092 (14.2)	571 (3.9)
Grade 1	1394 (9.2)	668 (4.4)	1735 (11.8)	523 (3.6)
Grade 2	110 (0.7)	27 (0.2)	289 (2.0)	28 (0.2)
Grade 3[d]	49 (0.3)	27 (0.2)	68 (0.5)	20 (0.1)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).

[c] Swelling: Grade 3 = > 100mm; Grade 4 = necrosis or exfoliative dermatitis.

[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2.

Table 30: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Positive				
	N=346	**N=337**	**N=232**	**N=233**
Any local AR	N1=346	N1=337	N1=232	N1=232
Any	250 (72.3)	60 (17.8)	172 (74.1)	42 (18.1)
Grade 1	180 (52.0)	56 (16.6)	125 (53.9)	35 (15.1)
Grade 2	56 (16.2)	1 (0.3)	36 (15.5)	5 (2.2)
Grade 3	14 (4.0)	3 (0.9)	11 (4.7)	2 (0.9)
Grade 4	0	0	0	0
Pain	N1=346	N1=337	N1=232	N1=232
Any	247 (71.4)	56 (16.6)	169 (72.8)	36 (15.5)
Grade 1	184 (53.2)	54 (16.0)	126 (54.3)	32 (13.8)
Grade 2	52 (15.0)	1 (0.3)	36 (15.5)	3 (1.3)
Grade 3[a]	11 (3.2)	1 (0.3)	7 (3.0)	1 (0.4)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=346	N1=337	N1=232	N1=232
Any	10 (2.9)	3 (0.9)	9 (3.9)	1 (0.4)
Grade 1	6 (1.7)	1 (0.3)	2 (0.9)	0
Grade 2	2 (0.6)	0	4 (1.7)	0
Grade 3	2 (0.6)	2 (0.6)	3 (1.3)	1 (0.4)
Grade 4	0	0	0	0
Swelling (hardness)	N1=346	N1=337	N1=232	N1=232
Any	19 (5.5)	2 (0.6)	11 (4.7)	1 (0.4)
Grade 1	10 (2.9)	2 (0.6)	4 (1.7)	0
Grade 2	8 (2.3)	0	5 (2.2)	1 (0.4)
Grade 3[c]	1 (0.3)	0	2 (0.9)	0
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=346	N1=337	N1=232	N1=232
Any	56 (16.2)	18 (5.3)	32 (13.8)	11 (4.7)
Grade 1	40 (11.6)	17 (5.0)	22 (9.5)	8 (3.4)
Grade 2	12 (3.5)	0	8 (3.4)	3 (1.3)
Grade 3[d]	4 (1.2)	1 (0.3)	2 (0.9)	0
Grade 4[d]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Negative				
	N=14733	**N=14730**	**N=14378**	**N=14267**
Any local AR	N1=14729	N1=14726	N1=14375	N1=14267
Any	12442 (84.5)	2934 (19.9)	12783 (88.9)	2699 (18.9)
Grade 1	10481 (71.2)	2771 (18.8)	8620 (60.0)	2543 (17.8)
Grade 2	1449 (9.8)	88 (0.6)	3160 (22.0)	83 (0.6)
Grade 3	512 (3.5)	75 (0.5)	1003 (7.0)	73 (0.5)
Grade 4	0	0	0	0
Pain	N1=14729	N1=14726	N1=14375	N1=14267
Any	12369 (84.0)	2596 (17.6)	12722 (88.5)	2435 (17.1)
Grade 1	10735 (72.9)	2484 (16.9)	9330 (64.9)	2337 (16.4)
Grade 2	1232 (8.4)	58 (0.4)	2797 (19.5)	58 (0.4)
Grade 3[a]	402 (2.7)	54 (0.4)	595 (4.1)	40 (0.3)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=14729	N1=14726	N1=14374	N1=14267
Any	429 (2.9)	74 (0.5)	1259 (8.8)	66 (0.5)
Grade 1	272 (1.8)	56 (0.4)	452 (3.1)	47 (0.3)
Grade 2	117 (0.8)	7 (<0.1)	527 (3.7)	5 (<0.1)
Grade 3	40 (0.3)	11 (<0.1)	280 (1.9)	14 (<0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=14729	N1=14726	N1=14374	N1=14267
Any	910 (6.2)	63 (0.4)	1783 (12.4)	59 (0.4)
Grade 1	593 (4.0)	48 (0.3)	890 (6.2)	38 (0.3)
Grade 2	236 (1.6)	9 (<0.1)	642 (4.5)	9 (<0.1)
Grade 3[c]	81 (0.5)	6 (<0.1)	251 (1.7)	12 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=14729	N1=14726	N1=14374	N1=14267
Any	1487 (10.1)	701 (4.8)	2047 (14.2)	557 (3.9)
Grade 1	1344 (9.1)	648 (4.4)	1704 (11.9)	512 (3.6)
Grade 2	98 (0.7)	27 (0.2)	277 (1.9)	25 (0.2)
Grade 3[d]	45 (0.3)	26 (0.2)	66 (0.5)	20 (0.1)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).

[c] Swelling: Grade 3 = >100mm; Grade 4 = necrosis or exfoliative dermatitis.
[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2.

Table 31: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥18 to <65				
	N=11406	**N=11402**	**N=11000**	**N=10929**
Any local AR	N1=11402	N1=11400	N1=10999	N1=10928
Any	9961 (87.4)	2436 (21.4)	9936 (90.3)	2262 (20.7)
Grade 1	8151 (71.5)	2334 (20.5)	6424 (58.4)	2145 (19.6)
Grade 2	1358 (11.9)	63 (0.6)	2709 (24.6)	73 (0.7)
Grade 3	452 (4.0)	39 (0.3)	803 (7.3)	44 (0.4)
Grade 4	0	0	0	0
Pain	N1=11402	N1=11400	N1=10999	N1=10928
Any	9908 (86.9)	2183 (19.1)	9893 (89.9)	2048 (18.7)
Grade 1	8360 (73.3)	2116 (18.6)	6933 (63.0)	1978 (18.1)
Grade 2	1182 (10.4)	44 (0.4)	2454 (22.3)	48 (0.4)
Grade 3[a]	366 (3.2)	23 (0.2)	506 (4.6)	22 (0.2)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=11402	N1=11400	N1=10998	N1=10928
Any	354 (3.1)	54 (0.5)	989 (9.0)	53 (0.5)
Grade 1	222 (1.9)	39 (0.3)	358 (3.3)	36 (0.3)
Grade 2	98 (0.9)	4 (<0.1)	421 (3.8)	5 (<0.1)
Grade 3	34 (0.3)	11 (<0.1)	210 (1.9)	12 (0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=11402	N1=11400	N1=10998	N1=10928
Any	766 (6.7)	42 (0.4)	1399 (12.7)	46 (0.4)
Grade 1	499 (4.4)	35 (0.3)	706 (6.4)	32 (0.3)
Grade 2	205 (1.8)	4 (<0.1)	510 (4.6)	9 (<0.1)
Grade 3[c]	62 (0.5)	3 (<0.1)	183 (1.7)	5 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=11402	N1=11400	N1=10998	N1=10928
Any	1322 (11.6)	567 (5.0)	1777 (16.2)	474 (4.3)
Grade 1	1180 (10.3)	534 (4.7)	1468 (13.3)	435 (4.0)
Grade 2	105 (0.9)	20 (0.2)	262 (2.4)	27 (0.2)
Grade 3[d]	37 (0.3)	13 (0.1)	47 (0.4)	12 (0.1)
Grade 4[d]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥ 65				
	N=3760	**N=3749**	**N=3691**	**N=3649**
Any local AR	N1=3760	N1=3747	N1=3689	N1=3649
Any	2804 (74.6)	573 (15.3)	3093 (83.8)	495 (13.6)
Grade 1	2574 (68.5)	508 (13.6)	2365 (64.1)	449 (12.3)
Grade 2	153 (4.1)	26 (0.7)	508 (13.8)	15 (0.4)
Grade 3	77 (2.0)	39 (1.0)	220 (6.0)	31 (0.8)
Grade 4	0	0	0	0
Pain	N1=3760	N1=3747	N1=3689	N1=3649
Any	2780 (73.9)	482 (12.9)	3071 (83.2)	438 (12.0)
Grade 1	2625 (69.8)	435 (11.6)	2575 (69.8)	406 (11.1)
Grade 2	105 (2.8)	15 (0.4)	396 (10.7)	13 (0.4)
Grade 3[a]	50 (1.3)	32 (0.9)	100 (2.7)	19 (0.5)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=3760	N1=3747	N1=3689	N1=3649
Any	91 (2.4)	23 (0.6)	285 (7.7)	15 (0.4)
Grade 1	59 (1.6)	18 (0.5)	98 (2.7)	12 (0.3)
Grade 2	24 (0.6)	3 (<0.1)	110 (3.0)	0
Grade 3	8 (0.2)	2 (<0.1)	77 (2.1)	3 (<0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=3760	N1=3747	N1=3689	N1=3649
Any	169 (4.5)	23 (0.6)	408 (11.1)	14 (0.4)
Grade 1	109 (2.9)	15 (0.4)	194 (5.3)	6 (0.2)
Grade 2	40 (1.1)	5 (0.1)	142 (3.8)	1 (<0.1)
Grade 3[c]	20 (0.5)	3 (<0.1)	72 (2.0)	7 (0.2)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=3760	N1=3747	N1=3689	N1=3649
Any	231 (6.1)	155 (4.1)	315 (8.5)	97 (2.7)
Grade 1	214 (5.7)	134 (3.6)	267 (7.2)	88 (2.4)
Grade 2	5 (0.1)	7 (0.2)	27 (0.7)	1 (<0.1)
Grade 3[d]	12 (0.3)	14 (0.4)	21 (0.6)	8 (0.2)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).
[c] Swelling: Grade 3 = >100mm; Grade 4 = necrosis or exfoliative dermatitis.
[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2.

5.2.1.2 Onset After 7 Days

Table 32: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1 N=15184	Placebo Dose 1 N=15162	mRNA-1273 Dose 2 N=14731	Placebo Dose 2 N=14631
Delayed local injection site reaction				
Any – n (%)	174 (1.1)	29 (0.2)	49 (0.3)	72 (0.5)
Severe – n (%)	8 (<0.1)	0	0	0
Medically attended– n (%)	13 (<0.1)	4 (<0.1)	4 (<0.1)	9 (<0.1)
SAE– n (%)	0	0	0	0
Day of onset: median (min, max)	9.0 (8, 34)	12.0 (8, 74)	11.0 (8, 76)	24.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.0 (1, 104)	4.0 (1, 141)	3.0 (1, 172)
Pain				
Any– n (%)	66 (0.4)	17 (0.1)	37 (0.3)	60 (0.4)
Severe– n (%)	2 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 34)	16.0 (8, 31)	13.0 (8, 54)	24.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.0 (1, 104)	4.0 (1, 31)	3.0 (1, 136)
Erythema (redness)				
Any – n (%)	89 (0.6)	9 (<0.1)	10 (<0.1)	8 (<0.1)
Severe – n (%)	6 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 29)	12.0 (8, 32)	8.5 (8, 76)	32.0 (8, 125)
Duration (days): median (min, max)	4.0 (1, 47)	4.0 (2, 58)	4.5 (1, 31)	13.0 (1, 172)
Swelling (hardness)				
Any– n (%)	62 (0.4)	6 (<0.1)	8 (<0.1)	6 (<0.1)
Severe– n (%)	1 (<0.1)	0	0	0
Day of onset: median (min, max)	9.0 (8, 32)	9.0 (8, 74)	8.0 (8, 43)	26.5 (8, 129)
Duration (days): median (min, max)	4.0 (1, 172)	3.0 (2, 8)	8.5 (2, 141)	3.5 (1, 158)

Abbreviations: IP=investigational product; max=maximum; min=minimum; SAE=serious adverse event.

Notes: Solicited (local) injection site reaction includes pain, erythema, and swelling. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants who received the corresponding injection (N).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.21.1.3.1, Table 14.3.1.21.1.3.2; Ad hoc Table 14.3.1.21.1.3.5.2, Ad hoc Table 14.3.1.21.1.3.6.2, Ad hoc Table 14.3.1.21.1.5.1.1, Ad hoc Table 14.3.1.21.1.5.1.2, Ad hoc Table 14.3.1.21.1.6.1.1, Ad hoc Table 14.3.1.21.1.6.1.2, Ad hoc Table 14.3.1.21.1.7.1.1, Ad hoc Table 14.3.1.21.1.7.1.2.

Table 33: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions, by Baseline SARS-CoV-2 Status (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Baseline SARS-CoV-2 Status Positive	**N=347**	**N=337**	**N=234**	**N=236**
Delayed local injection site reaction				
Any – n (%)	1 (0.3)	2 (0.6)	0	1 (0.4)
Severe – n (%)	0	0	0	0
Medically attended– n (%)	0	0	0	1 (0.4)
SAE– n (%)	0	0	0	0
Day of onset: median (min, max)	14.0 (14, 14)	44.5 (15, 74)	NA	9.0 (9, 9)
Duration (days): median (min, max)	1.0 (1, 1)	12.0 (8, 16)	NA	3.0 (3, 3)
Pain				
Any– n (%)	1 (0.3)	0	0	1 (0.4)
Severe– n (%)	0	0	0	0
Day of onset: median (min, max)	14.0 (14, 14)	NA	NA	9.0 (9, 9)
Duration (days): median (min, max)	1.0 (1, 1)	NA	NA	3.0 (3, 3)
Erythema (redness)				
Any – n (%)	0	1 (0.3)	0	0
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	NA	15.0 (15, 15)	NA	NA
Duration (days): median (min, max)	NA	16.0 (16, 16)	NA	NA
Swelling (hardness)				
Any – n (%)	0	1 (0.3)	0	0
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	NA	74.0 (74, 74)	NA	NA
Duration (days): median (min, max)	NA	8.0 (8, 8)	NA	NA
Baseline SARS-CoV-2 Status Negative	**N=14750**	**N=14741**	**N=14416**	**N=14316**
Delayed local injection site reaction				
Any– n (%)	173 (1.2)	27 (0.2)	49 (0.3)	70 (0.5)
Severe– n (%)	8 (<0.1)	0	0	0
Medically attended– n (%)	13 (<0.1)	4 (<0.1)	4 (<0.1)	8 (<0.1)
SAE– n (%)	0	0	0	0
Day of onset: median (min, max)	9.0 (8, 34)	12.0 (8, 32)	11.0 (8, 76)	24.5 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.0 (1, 104)	4.0 (1, 141)	3.0 (1, 172)
Pain				
Any– n (%)	65 (0.4)	17 (0.1)	37 (0.3)	58 (0.4)
Severe– n (%)	2 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 34)	16.0 (8, 31)	13.0 (8, 54)	25.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.0 (1, 104)	4.0 (1, 31)	3.0 (1, 136)
Erythema (redness)				
Any – n (%)	89 (0.6)	8 (0.1)	10 (0.1)	8 (0.1)
Severe – n (%)	6 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 29)	10.5 (8, 32)	8.5 (8, 76)	32.0 (8, 125)
Duration (days): median (min, max)	4.0 (1, 47)	3.5 (2, 58)	4.5 (1, 31)	13.0 (1, 172)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Swelling (hardness)				
Any– n (%)	62 (0.4)	5 (<0.1)	8 (0.1)	6 (<0.1)
Severe– n (%)	1 (<0.1)	0	0	0
Day of onset: median (min, max)	9.0 (8, 32)	8.0 (8, 12)	8.0 (8, 43)	26.5 (8, 129)
Duration (days): median (min, max)	4.0 (1, 172)	3.0 (2, 4)	8.5 (2, 141)	3.5 (1, 158)

Abbreviations: IP=investigational product; max=maximum; min=minimum; SAE=serious adverse event.

Notes: Solicited (local) injection site reaction includes pain, erythema, and swelling. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants who received the corresponding injection (N).

Source: Ad hoc Table 14.3.1.21.1.3.5.3, Ad hoc Table 14.3.1.21.1.3.6.3, Ad hoc Table 14.3.1.21.1.5.2.1, Ad hoc Table 14.3.1.21.1.5.2.2, Ad hoc Table 14.3.1.21.1.6.2.1, Ad hoc Table 14.3.1.21.1.6.2.2, Ad hoc Table 14.3.1.21.1.7.2.1, Ad hoc Table 14.3.1.21.1.7.2.2.

Table 34: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions, by Age Group (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Age ≥18 to <65	**N=11415**	**N=11411**	**N=11027**	**N=10964**
Delayed local injection site reaction				
Any – n (%)	131 (1.1)	20 (0.2)	29 (0.3)	53 (0.5)
Severe – n (%)	4 (<0.1)	0	0	0
Medically attended– n (%)	9 (<0.1)	2 (<0.1)	2 (<0.1)	7 (<0.1)
SAE– n (%)	0	0	0	0
Day of onset: median (min, max)	9.0 (8, 34)	11.5 (8, 31)	10.0 (8, 76)	24.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.0 (1, 104)	5.0 (1, 31)	3.0 (1, 158)
Pain				
Any– n (%)	54 (0.5)	14 (0.1)	25 (0.2)	45 (0.4)
Severe– n (%)	1 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 34)	16.0 (8, 31)	10.0 (8, 54)	22.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 183)	6.5 (1, 104)	4.0 (1, 31)	3.0 (1, 136)
Erythema (redness)				
Any – n (%)	62 (0.5)	5 (<0.1)	4 (<0.1)	5 (<0.1)
Severe – n (%)	3 (<0.1)	0	0	0
Day of onset: median (min, max)	9.0 (8, 29)	9.0 (8, 15)	8.0 (8, 76)	25.0 (8, 125)
Duration (days): median (min, max)	4.0 (1, 47)	3.0 (2, 16)	8.0 (2, 31)	15.0 (1, 59)
Swelling (hardness)				
Any – n (%)	51 (0.4)	4 (<0.1)	3 (<0.1)	3 (<0.1)
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	9.0 (8, 32)	9.0 (8, 12)	8.0 (8, 8)	10.0 (8, 35)
Duration (days): median (min, max)	5.0 (1, 172)	3.0 (2, 4)	9.0 (2, 25)	4.0 (1, 158)
Age ≥ 65	**N=3769**	**N=3751**	**N=3704**	**N=3667**
Delayed local injection site reaction				
Any– n (%)	43 (1.1)	9 (0.2)	20 (0.5)	19 (0.5)
Severe– n (%)	4 (0.1)	0	0	0
Medically attended– n (%)	4 (0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)
SAE– n (%)	0	0	0	0
Day of onset: median (min, max)	10.0 (8, 31)	18.0 (8, 74)	15.5 (8, 51)	34.0 (8, 129)
Duration (days): median (min, max)	4.0 (1, 39)	6.0 (1, 58)	2.5 (1, 141)	3.0 (1, 172)
Pain				
Any– n (%)	12 (0.3)	3 (<0.1)	12 (0.3)	15 (0.4)
Severe– n (%)	1 (<0.1)	0	0	0
Day of onset: median (min, max)	12.5 (8, 30)	26.0 (8, 27)	16.0 (8, 47)	34.0 (8, 127)
Duration (days): median (min, max)	3.5 (1, 39)	3.0 (1, 6)	2.5 (1, 8)	3.0 (1, 10)
Erythema (redness)				
Any – n (%)	27 (0.7)	4 (0.1)	6 (0.2)	3 (<0.1)
Severe – n (%)	3 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (8, 15)	15.0 (9, 32)	9.0 (8, 51)	52.0 (8, 64)
Duration (days): median (min, max)	3.0 (1, 15)	33.0 (3, 58)	3.0 (1, 5)	11.0 (10, 172)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Swelling (hardness)				
Any– n (%)	11 (0.3)	2 (<0.1)	5 (0.1)	3 (<0.1)
Severe– n (%)	1 (<0.1)	0	0	0
Day of onset: median (min, max)	10.0 (9, 31)	41.0 (8, 74)	15.0 (8, 43)	52.0 (18, 129)
Duration (days): median (min, max)	4.0 (1, 13)	5.0 (2, 8)	8.0 (2, 141)	3.0 (3, 15)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum; SAE=serious adverse event.

Notes: Solicited (local) injection site reaction includes pain, erythema, and swelling. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1) or second injection (Dose 2).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.21.1.3.1, Table 14.3.1.21.1.3.2; Ad hoc Table 14.3.1.21.1.3.5.4, Ad hoc Table 14.3.1.21.1.3.6.4, Ad hoc Table 14.3.1.21.1.5.3.1, Ad hoc Table 14.3.1.21.1.5.3.2, Ad hoc Table 14.3.1.21.1.6.3.1, Ad hoc Table 14.3.1.21.1.6.3.2, Ad hoc Table 14.3.1.21.1.7.3.1, Ad hoc Table 14.3.1.21.1.7.3.2.

5.2.1.3 Overall Characteristics

Table 35: (Table X) Characteristics of Solicited Local Adverse Reactions (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Any local adverse reaction – n/N1 (%)	12765/15162 (84.2)	3009/15147 (19.9)	13029/14688 (88.7)	2757/14577 (18.9)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 71)	1.0 (1, 51)	3.0 (1, 154)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	361/15162 (2.4)	133/15147 (0.9)	315/14688 (2.1)	124/14577 (0.9)
Pain – n/N1 (%)	12688/15162 (83.7)	2665/15147 (17.6)	12964/14688 (88.3)	2486/14577 (17.1)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 69)	1.0 (1, 51)	3.0 (1, 154)	1.0 (1, 159)
Persisted beyond 7 days, n/N1 (%)	101/15162 (0.7)	57/15147 (0.4)	158/14688 (1.1)	58/14577 (0.4)
Erythema (redness) – n/N1 (%)	445/15162 (2.9)	77/15147 (0.5)	1274/14687 (8.7)	68/14577 (0.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 41)	1.0 (1, 28)	2.0 (1, 39)	1.0 (1, 29)
Persisted beyond 7 days, n/N1 (%)	35/15162 (0.2)	20/15147 (0.1)	71/14687 (0.5)	13/14577 (<0.1)
Swelling (hardness) – n/N1 (%)	935/15162 (6.2)	65/15147 (0.4)	1807/14687 (12.3)	60/14577 (0.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	1.0 (1, 36)	2.0 (1, 33)	2.0 (1, 31)	1.0 (1, 31)
Persisted beyond 7 days, n/N1 (%)	33/15162 (0.2)	22/15147 (0.1)	70/14687 (0.5)	16/14577 (0.1)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Axillary swelling or tenderness – n/N1 (%)	1553/15162 (10.2)	722/15147 (4.8)	2092/14687 (14.2)	571/14577 (3.9)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 69)	1.0 (1, 33)	2.0 (1, 151)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	234/15162 (1.5)	57/15147 (0.4)	96/14687 (0.7)	51/14577 (0.3)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.3.1.4.1.1, Table 14.3.1.4.1.2, Table 14.3.1.6.1.1, Table 14.3.1.6.1.2; Ad hoc Table 14.3.1.3.6.3.1, Ad hoc Table 14.3.1.3.6.3.2.

Table 36: (Table X) Characteristics of Solicited Local Adverse Reactions, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Baseline SARS-CoV-2 Status Positive				
Any local adverse reaction – n/N1 (%)	250/346 (72.3)	60/337 (17.8)	172/232 (74.1)	42/232 (18.1)
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 6)
Duration (days): median (min, max)	2.0 (1, 16)	1.0 (1, 10)	2.0 (1, 154)	1.0 (1, 18)
Persisted beyond 7 days, n/N1 (%)	4/346 (1.2)	4/337 (1.2)	3/232 (1.3)	4/232 (1.7)
Pain – n/N1 (%)	247/346 (71.4)	56/337 (16.6)	169/232 (72.8)	36/232 (15.5)
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 5)
Duration: median (min, max)	2.0 (1, 7)	1.0 (1, 9)	2.0 (1, 154)	1.0 (1, 5)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	1/337 (0.3)	3/232 (1.3)	0
Erythema (redness) – n/N1 (%)	10/346 (2.9)	3/337 (0.9)	9/232 (3.9)	1/232 (0.4)
Day of onset: median (min, max)	2.5 (1, 6)	3.0 (2, 4)	3.0 (1, 4)	3.0 (3, 3)
Duration: median (min, max)	1.0 (1, 7)	1.0 (1, 1)	3.0 (1, 18)	2.0 (2, 2)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	0	1/232 (0.4)	0
Swelling (hardness) – n/N1 (%)	19/346 (5.5)	2/337 (0.6)	11/232 (4.7)	1/232 (0.4)
Day of onset: median (min, max)	2.0 (1, 6)	1.5 (1, 2)	2.0 (1, 5)	5.0 (5, 5)
Duration: median (min, max)	1.0 (1, 15)	1.5 (1, 2)	3.0 (1, 18)	1.0 (1, 1)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	0	2/232 (0.9)	0
Axillary swelling or tenderness – n/N1 (%)	56/346 (16.2)	18/337 (5.3)	32/232 (13.8)	11/232 (4.7)
Day of onset: median (min, max)	2.0 (1, 7)	5.0 (1, 7)	2.0 (1, 4)	2.0 (1, 6)
Duration: median (min, max)	1.0 (1, 6)	1.5 (1, 10)	1.5 (1, 7)	4.0 (1, 17)
Persisted beyond 7 days, n/N1 (%)	2/346 (0.6)	4/337 (1.2)	1/232 (0.4)	4/232 (1.7)
Baseline SARS-CoV-2 Status Negative				
Any local adverse reaction – n/N1 (%)	12442/14729 (84.5)	2934/14726 (19.9)	12783/14375 (88.9)	2699/14267 (18.9)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 71)	1.0 (1, 51)	3.0 (1, 151)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	356/14729 (2.4)	128/14726 (0.9)	311/14375 (2.2)	119/14267 (0.8)
Pain – n/N1 (%)	12369/14729 (84.0)	2596/14726 (17.6)	12722/14375 (88.5)	2435/14267 (17.1)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 69)	1.0 (1, 51)	3.0 (1, 147)	1.0 (1, 159)
Persisted beyond 7 days, n/N1 (%)	100/14729 (0.7)	56/14726 (0.4)	154/14375 (1.1)	57/14267 (0.4)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Erythema (redness) – n/N1 (%)	429/14729 (2.9)	74/14726 (0.5)	1259/14374 (8.8)	66/14267 (0.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 41)	1.0 (1, 28)	2.0 (1, 39)	1.0 (1, 29)
Persisted beyond 7 days, n/N1 (%)	34/14729 (0.2)	20/14726 (0.1)	70/14374 (0.5)	13/14267 (<0.1)
Swelling (hardness) – n/N1 (%)	910/14729 (6.2)	63/14726 (0.4)	1783/14374 (12.4)	59/14267 (0.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 36)	3.0 (1, 33)	2.0 (1, 31)	1.0 (1, 31)
Persisted beyond 7 days, n/N1 (%)	32/14729 (0.2)	22/14726 (0.1)	68/14374 (0.5)	16/14267 (0.1)
Axillary swelling or tenderness – n/N1 (%)	1487/14729 (10.1)	701/14726 (4.8)	2047/14374 (14.2)	557/14267 (3.9)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 69)	1.0 (1, 33)	2.0 (1, 151)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	231/14729 (1.6)	52/14726 (0.4)	95/14374 (0.7)	47/14267 (0.3)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2, Table 14.3.1.4.3.1, Table 14.3.1.4.3.2, Table 14.3.1.6.3.1, Table 14.3.1.6.3.2; Ad hoc Table 14.3.1.3.6.4.1, Ad hoc Table 14.3.1.3.6.4.2.

Table 37: (Table X) Characteristics of Solicited Local Adverse Reactions, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Age ≥18 to <65				
Any local adverse reaction – n/N1 (%)	9961/11402 (87.4)	2436/11400 (21.4)	9936/10999 (90.3)	2262/10928 (20.7)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 71)	1.0 (1, 35)	3.0 (1, 154)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	325/11402 (2.9)	98/11400 (0.9)	234/10999 (2.1)	102/10928 (0.9)
Pain – n/N1 (%)	9908/11402 (86.9)	2183/11400 (19.1)	9893/10999 (89.9)	2048/10928 (18.7)
Day of onset: median (min, max)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 69)	1.0 (1, 35)	3.0 (1, 154)	1.0 (1, 159)
Persisted beyond 7 days, n/N1 (%)	89/11402 (0.8)	45/11400 (0.4)	115/10999 (1.0)	46/10928 (0.4)
Erythema (redness) – n/N1 (%)	354/11402 (3.1)	54/11400 (0.5)	989/10998 (9.0)	53/10928 (0.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 41)	1.0 (1, 28)	2.0 (1, 24)	2.0 (1, 29)
Persisted beyond 7 days, n/N1 (%)	25/11402 (0.2)	11/11400 (<0.1)	40/10998 (0.4)	10/10928 (<0.1)
Swelling (hardness) – n/N1 (%)	766/11402 (6.7)	42/11400 (0.4)	1399/10998 (12.7)	46/10928 (0.4)
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	2.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 36)	2.0 (1, 33)	2.0 (1, 31)	2.0 (1, 17)
Persisted beyond 7 days, n/N1 (%)	28/11402 (0.2)	11/11400 (<0.1)	48/10998 (0.4)	13/10928 (0.1)
Axillary swelling or tenderness – n/N1 (%)	1322/11402 (11.6)	567/11400 (5.0)	1777/10998 (16.2)	474/10928 (4.3)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 69)	1.0 (1, 33)	2.0 (1, 151)	1.0 (1, 212)
Persisted beyond 7 days, n/N1 (%)	223/11402 (2.0)	49/11400 (0.4)	89/10998 (0.8)	46/10928 (0.4)
Age ≥ 65				
Any local adverse reaction – n/N1 (%)	2804/3760 (74.6)	573/3747 (15.3)	3093/3689 (83.8)	495/3649 (13.6)
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 41)	1.0 (1, 51)	3.0 (1, 147)	1.0 (1, 31)
Persisted beyond 7 days, n/N1 (%)	36/3760 (1.0)	35/3747 (0.9)	81/3689 (2.2)	22/3649 (0.6)
Pain – n/N1 (%)	2780/3760 (73.9)	482/3747 (12.9)	3071/3689 (83.2)	438/3649 (12.0)
Day of onset: median (min, max)	2.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: median (min, max)	2.0 (1, 41)	1.0 (1, 51)	3.0 (1, 147)	1.0 (1, 13)
Persisted beyond 7 days, n/N1 (%)	12/3760 (0.3)	12/3747 (0.3)	43/3689 (1.2)	12/3649 (0.3)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Erythema (redness) – n/N1 (%)	91/3760 (2.4)	23/3747 (0.6)	285/3689 (7.7)	15/3649 (0.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 5)	2.0 (1, 7)	1.0 (1, 6)
Duration: median (min, max)	2.0 (1, 35)	1.0 (1, 27)	2.0 (1, 39)	1.0 (1, 26)
Persisted beyond 7 days, n/N1 (%)	10/3760 (0.3)	9/3747 (0.2)	31/3689 (0.8)	3/3649 (<0.1)
Swelling (hardness) – n/N1 (%)	169/3760 (4.5)	23/3747 (0.6)	408/3689 (11.1)	14/3649 (0.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 6)	1.0 (1, 4)
Duration: median (min, max)	1.0 (1, 21)	4.0 (1, 29)	2.0 (1, 12)	1.0 (1, 31)
Persisted beyond 7 days, n/N1 (%)	5/3760 (0.1)	11/3747 (0.3)	22/3689 (0.6)	3/3649 (<0.1)
Axillary swelling or tenderness – n/N1 (%)	231/3760 (6.1)	155/3747 (4.1)	315/3689 (8.5)	97/3649 (2.7)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 24)	1.0 (1, 16)	1.0 (1, 9)	1.0 (1, 14)
Persisted beyond 7 days, n/N1 (%)	11/3760 (0.3)	8/3747 (0.2)	7/3689 (0.2)	5/3649 (0.1)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2, Table 14.3.1.4.2.1, Table 14.3.1.4.2.2, Table 14.3.1.6.2.1, Table 14.3.1.6.2.2; Ad hoc Table 14.3.1.3.6.5.1, Ad hoc Table 14.3.1.3.6.5.2.

5.2.2 Systemic Adverse Reactions

5.2.2.1 Onset Within 7 Days

Table 38: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 N=15166 Dose 1 n (%)	Placebo N=15151 Dose 1 n (%)	mRNA-1273 N=14691 Dose 2 n (%)	Placebo N=14578 Dose 2 n (%)
Any systemic AR	N1=15166	N1=15151	N1=14690	N1=14577
Any	8316 (54.8)	6397 (42.2)	11678 (79.5)	5343 (36.7)
Grade 1	5358 (35.3)	4334 (28.6)	3717 (25.3)	3519 (24.1)
Grade 2	2504 (16.5)	1746 (11.5)	5611 (38.2)	1535 (10.5)

Event	mRNA-1273 N=15166 Dose 1 n (%)	Placebo N=15151 Dose 1 n (%)	mRNA-1273 N=14691 Dose 2 n (%)	Placebo N=14578 Dose 2 n (%)
Grade 3	449 (3.0)	311 (2.1)	2336 (15.9)	286 (2.0)
Grade 4	5 (<0.1)	6 (<0.1)	14 (<0.1)	3 (<0.1)
Fever[a]	N1=15163	N1=15149	N1=14682	N1=14573
≥38.0°C	112 (0.7)	44 (0.3)	2276 (15.5)	43 (0.3)
38.0°C to 38.4°C	73 (0.5)	28 (0.2)	1363 (9.3)	33 (0.2)
38.5°C to 38.9°C	24 (0.2)	8 (<0.1)	697 (4.7)	5 (<0.1)
39°C to 40.0°C	11 (<0.1)	2 (<0.1)	203 (1.4)	2 (<0.1)
>40.0°C	4 (<0.1)	6 (<0.1)	13 (<0.1)	3 (<0.1)
Headache	N1=15162	N1=15146	N1=14687	N1=14575
Any	4950 (32.6)	4026 (26.6)	8637 (58.8)	3427 (23.5)
Grade 1	3947 (26.0)	3297 (21.8)	4815 (32.8)	2740 (18.8)
Grade 2	730 (4.8)	532 (3.5)	3156 (21.5)	522 (3.6)
Grade 3[b]	273 (1.8)	197 (1.3)	666 (4.5)	165 (1.1)
Grade 4[b]	0	0	0	0
Fatigue	N1=15162	N1=15146	N1=14687	N1=14575
Any	5636 (37.2)	4133 (27.3)	9607 (65.4)	3418 (23.5)
Grade 1	3585 (23.6)	2705 (17.9)	3431 (23.4)	2181 (15.0)
Grade 2	1899 (12.5)	1323 (8.7)	4743 (32.3)	1129 (7.7)
Grade 3[c]	151 (1.0)	105 (0.7)	1433 (9.8)	108 (0.7)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=15162	N1=15146	N1=14687	N1=14575
Any	3442 (22.7)	2069 (13.7)	8529 (58.1)	1824 (12.5)
Grade 1	2442 (16.1)	1560 (10.3)	3242 (22.1)	1307 (9.0)
Grade 2	909 (6.0)	462 (3.1)	3966 (27.0)	465 (3.2)
Grade 3[c]	91 (0.6)	47 (0.3)	1321 (9.0)	52 (0.4)
Grade 4[c]	0	0	0	0
Arthralgia	N1=15162	N1=15146	N1=14687	N1=14575
Any	2510 (16.6)	1784 (11.8)	6303 (42.9)	1579 (10.8)
Grade 1	1842 (12.1)	1333 (8.8)	2809 (19.1)	1143 (7.8)
Grade 2	607 (4.0)	413 (2.7)	2719 (18.5)	392 (2.7)
Grade 3[c]	60 (0.4)	38 (0.3)	775 (5.3)	44 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0
Nausea/vomiting	N1=15162	N1=15146	N1=14687	N1=14575
Any	1262 (8.3)	1075 (7.1)	2794 (19.0)	941 (6.5)
Grade 1	1047 (6.9)	887 (5.9)	2094 (14.3)	761 (5.2)
Grade 2	205 (1.4)	175 (1.2)	678 (4.6)	169 (1.2)
Grade 3[d]	10 (<0.1)	13 (<0.1)	21 (0.1)	11 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=15162	N1=15146	N1=14687	N1=14575
Any	1251 (8.3)	878 (5.8)	6500 (44.3)	813 (5.6)
Grade 1	938 (6.2)	706 (4.7)	2907 (19.8)	629 (4.3)
Grade 2	289 (1.9)	158 (1.0)	3402 (23.2)	167 (1.1)
Grade 3[e]	24 (0.2)	14 (<0.1)	191 (1.3)	17 (0.1)
Grade 4[e]	0	0	0	0

Event	mRNA-1273 N=15166 Dose 1 n (%)	Placebo N=15151 Dose 1 n (%)	mRNA-1273 N=14691 Dose 2 n (%)	Placebo N=14578 Dose 2 n (%)
Use of antipyretic or pain medication	3329 (22.0)	2000 (13.2)	7855 (53.5)	1585 (10.9)

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1). Medications were collected on the eDiary.

[a] Fever is defined as: Grade 1=38°C to 38.4°C; Grade 2=38.5°C to 38.9°C; Grade 3=39°C to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.1.5.5.1, Table 14.1.5.5.2.

Table 39: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Positive				
	N=346	**N=337**	**N=232**	**N=233**
Any systemic AR	N1=346	N1=337	N1=232	N1=233
Any	214 (61.8)	122 (36.2)	152 (65.5)	73 (31.3)
Grade 1	108 (31.2)	70 (20.8)	61 (26.3)	44 (18.9)
Grade 2	82 (23.7)	40 (11.9)	70 (30.2)	28 (12.0)
Grade 3	23 (6.6)	11 (3.3)	21 (9.1)	1 (0.4)
Grade 4	1 (0.3)	1 (0.3)	0	0
Fever[a]	N1=346	N1=336	N1=232	N1=232
≥38.0°C	33 (9.5)	6 (1.8)	31 (13.4)	1 (0.4)
38.0°C to 38.4°C	20 (5.8)	3 (0.9)	20 (8.6)	1 (0.4)
38.5°C to 38.9°C	10 (2.9)	2 (0.6)	9 (3.9)	0
39°C to 40.0°C	2 (0.6)	0	2 (0.9)	0
>40.0°C	1 (0.3)	1 (0.3)	0	0
Headache	N1=346	N1=337	N1=232	N1=232
Any	134 (38.7)	83 (24.6)	98 (42.2)	43 (18.5)
Grade 1	89 (25.7)	60 (17.8)	61 (26.3)	35 (15.1)
Grade 2	33 (9.5)	16 (4.7)	31 (13.4)	8 (3.4)
Grade 3[b]	12 (3.5)	7 (2.1)	6 (2.6)	0
Grade 4[b]	0	0	0	0
Fatigue	N1=346	N1=337	N1=232	N1=232
Any	138 (39.9)	72 (21.4)	106 (45.7)	54 (23.3)
Grade 1	71 (20.5)	40 (11.9)	42 (18.1)	31 (13.4)
Grade 2	57 (16.5)	28 (8.3)	52 (22.4)	22 (9.5)
Grade 3[c]	10 (2.9)	4 (1.2)	12 (5.2)	1 (0.4)
Grade 4[c]	0	0	0	0
Myalgia	N1=346	N1=337	N1=232	N1=232
Any	128 (37.0)	47 (13.9)	117 (50.4)	34 (14.7)
Grade 1	71 (20.5)	27 (8.0)	60 (25.9)	22 (9.5)
Grade 2	50 (14.5)	18 (5.3)	46 (19.8)	12 (5.2)
Grade 3[c]	7 (2.0)	2 (0.6)	11 (4.7)	0
Grade 4[c]	0	0	0	0
Arthralgia	N1=346	N1=337	N1=232	N1=232
Any	88 (25.4)	40 (11.9)	77 (33.2)	26 (11.2)
Grade 1	54 (15.6)	21 (6.2)	37 (15.9)	19 (8.2)
Grade 2	29 (8.4)	17 (5.0)	36 (15.5)	7 (3.0)
Grade 3[c]	5 (1.4)	2 (0.6)	4 (1.7)	0
Grade 4[c]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Nausea/vomiting	N1=346	N1=337	N1=232	N1=232
Any	43 (12.4)	25 (7.4)	33 (14.2)	13 (5.6)
Grade 1	30 (8.7)	17 (5.0)	25 (10.8)	10 (4.3)
Grade 2	13 (3.8)	8 (2.4)	7 (3.0)	3 (1.3)
Grade 3[d]	0	0	1 (0.4)	0
Grade 4[d]	0	0	0	0
Chills	N1=346	N1=337	N1=232	N1=232
Any	81 (23.4)	27 (8.0)	80 (34.5)	19 (8.2)
Grade 1	43 (12.4)	17 (5.0)	40 (17.2)	16 (6.9)
Grade 2	35 (10.1)	9 (2.7)	40 (17.2)	3 (1.3)
Grade 3[e]	3 (0.9)	1 (0.3)	0	0
Grade 4[e]	0	0	0	0
Baseline SARS-CoV-2 Status Negative				
	N=14733	**N=14730**	**N=14378**	**N=14267**
Any systemic AR	N1=14733	N1=14730	N1=14377	N1=14266
Any	8053 (54.7)	6239 (42.4)	5241 (36.7)	11459 (79.7)
Grade 1	5214 (35.4)	4234 (28.7)	3642 (25.3)	3453 (24.2)
Grade 2	2412 (16.4)	1701 (11.5)	5498 (38.2)	1500 (10.5)
Grade 3	423 (2.9)	299 (2.0)	2305 (16.0)	285 (2.0)
Grade 4	4 (<0.1)	5 (<0.1)	14 (<0.1)	3 (<0.1)
Fever[a]	N1=14731	N1=14729	N1=14370	N1=14263
≥38.0°C	78 (0.5)	38 (0.3)	2235 (15.6)	42 (0.3)
38.0°C to 38.4°C	52 (0.4)	25 (0.2)	1340 (9.3)	32 (0.2)
38.5°C to 38.9°C	14 (<0.1)	6 (<0.1)	682 (4.7)	5 (<0.1)
39°C to 40.0°C	9 (<0.1)	2 (<0.1)	200 (1.4)	2 (<0.1)
>40.0°C	3 (<0.1)	5 (<0.1)	13 (<0.1)	3 (<0.1)
Headache	N1=14729	N1=14725	N1=14374	N1=14265
Any	4787 (32.5)	3917 (26.6)	8488 (59.1)	3363 (23.6)
Grade 1	3833 (26.0)	3214 (21.8)	4725 (32.9)	2688 (18.8)
Grade 2	695 (4.7)	514 (3.5)	3105 (21.6)	510 (3.6)
Grade 3[b]	259 (1.8)	189 (1.3)	658 (4.6)	165 (1.2)
Grade 4[b]	0	0	0	0
Fatigue	N1=14729	N1=14725	N1=14374	N1=14265
Any	5466 (37.1)	4038 (27.4)	9446 (65.7)	3344 (23.4)
Grade 1	3490 (23.7)	2646 (18.0)	3375 (23.5)	2134 (15.0)
Grade 2	1834 (12.5)	1292 (8.8)	4655 (32.4)	1103 (7.7)
Grade 3[c]	141 (1.0)	100 (0.7)	1416 (9.9)	107 (0.8)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=14729	N1=14725	N1=14374	N1=14265
Any	3295 (22.4)	2011 (13.7)	8357 (58.1)	1775 (12.4)
Grade 1	2355 (16.0)	1524 (10.3)	3166 (22.0)	1271 (8.9)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Grade 2	857 (5.8)	443 (3.0)	3886 (27.0)	452 (3.2)
Grade 3[c]	83 (0.6)	44 (0.3)	1305 (9.1)	52 (0.4)
Grade 4[c]	0	0	0	0
Arthralgia	N1=14729	N1=14725	N1=14374	N1=14265
Any	2406 (16.3)	1735 (11.8)	6181 (43.0)	1543 (10.8)
Grade 1	1776 (12.1)	1305 (8.9)	2758 (19.2)	1115 (7.8)
Grade 2	574 (3.9)	395 (2.7)	2655 (18.5)	384 (2.7)
Grade 3[c]	55 (0.4)	35 (0.2)	768 (5.3)	44 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0
Nausea/vomiting	N1=14729	N1=14725	N1=14374	N1=14265
Any	1210 (8.2)	1044 (7.1)	2741 (19.1)	922 (6.5)
Grade 1	1009 (6.9)	866 (5.9)	2052 (14.3)	747 (5.2)
Grade 2	191 (1.3)	165 (1.1)	668 (4.6)	164 (1.1)
Grade 3[d]	10 (<0.1)	13 (<0.1)	20 (0.1)	11 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=14729	N1=14725	N1=14374	N1=14265
Any	1162 (7.9)	846 (5.7)	6384 (44.4)	790 (5.5)
Grade 1	891 (6.0)	684 (4.6)	2854 (19.9)	610 (4.3)
Grade 2	250 (1.7)	149 (1.0)	3340 (23.2)	163 (1.1)
Grade 3[e]	21 (0.1)	13 (<0.1)	190 (1.3)	17 (0.1)
Grade 4[e]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Fever is defined as: Grade 1=38 to 38.4°C; Grade 2=38.5 to 38.9°C; Grade 3=39 to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2.

Table 40: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥18 to <65				
	N=11406	**N=11402**	**N=11000**	**N=10929**
Any systemic AR	N1=11406	N1=11402	N1=10999	N1=10928
Any	6499 (57.0)	5063 (44.4)	9023 (82.0)	4208 (38.5)
Grade 1	4079 (35.8)	3367 (29.5)	2615 (23.8)	2731 (25.0)
Grade 2	2050 (18.0)	1442 (12.6)	4458 (40.5)	1248 (11.4)
Grade 3	365 (3.2)	250 (2.2)	1938 (17.6)	227 (2.1)
Grade 4	5 (<0.1)	4 (<0.1)	12 (0.1)	2 (<0.1)
Fever[a]	N1=11404	N1=11400	N1=10993	N1=10925
≥38.0°C	102 (0.9)	37 (0.3)	1909 (17.4)	38 (0.3)
38.0°C to 38.4°C	66 (0.6)	25 (0.2)	1112 (10.1)	30 (0.3)
38.5°C to 38.9°C	22 (0.2)	7 (<0.1)	600 (5.5)	4 (<0.1)
39°C to 40.0°C	10 (<0.1)	1 (<0.1)	185 (1.7)	2 (<0.1)
>40.0°C	4 (<0.1)	4 (<0.1)	12 (0.1)	2 (<0.1)
Headache	N1=11402	N1=11400	N1=10998	N1=10926
Any	4028 (35.3)	3303 (29.0)	6929 (63.0)	2775 (25.4)
Grade 1	3168 (27.8)	2668 (23.4)	3669 (33.4)	2182 (20.0)
Grade 2	640 (5.6)	472 (4.1)	2701 (24.6)	461 (4.2)
Grade 3[b]	220 (1.9)	163 (1.4)	559 (5.1)	132 (1.2)
Grade 4[b]	0	0	0	0
Fatigue	N1=11402	N1=11400	N1=10998	N1=10926
Any	4385 (38.5)	3281 (28.8)	7453 (67.8)	2701 (24.7)
Grade 1	2732 (24.0)	2100 (18.4)	2527 (23.0)	1701 (15.6)
Grade 2	1531 (13.4)	1098 (9.6)	3748 (34.1)	912 (8.3)
Grade 3[c]	121 (1.1)	83 (0.7)	1178 (10.7)	88 (0.8)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=11402	N1=11400	N1=10998	N1=10926
Any	2700 (23.7)	1625 (14.3)	6789 (61.7)	1425 (13.0)
Grade 1	1874 (16.4)	1200 (10.5)	2415 (22.0)	1002 (9.2)
Grade 2	752 (6.6)	387 (3.4)	3258 (29.6)	381 (3.5)
Grade 3[c]	74 (0.6)	38 (0.3)	1116 (10.1)	42 (0.4)
Grade 4[c]	0	0	0	0
Arthralgia	N1=11402	N1=11400	N1=10998	N1=10926
Any	1892 (16.6)	1327 (11.6)	5010 (45.6)	1180 (10.8)
Grade 1	1368 (12.0)	966 (8.5)	2111 (19.2)	841 (7.7)
Grade 2	476 (4.2)	331 (2.9)	2249 (20.4)	302 (2.8)
Grade 3[c]	47 (0.4)	30 (0.3)	650 (5.9)	37 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Nausea/vomiting	N1=11402	N1=11400	N1=10998	N1=10926
Any	1068 (9.4)	908 (8.0)	2355 (21.4)	807 (7.4)
Grade 1	889 (7.8)	749 (6.6)	1755 (16.0)	651 (6.0)
Grade 2	173 (1.5)	151 (1.3)	589 (5.4)	148 (1.4)
Grade 3[d]	6 (<0.1)	8 (<0.1)	11 (0.1)	8 (<0.1)
Grade 4[d]	0	0	0	0
Chills	N1=11402	N1=11400	N1=10998	N1=10926
Any	1050 (9.2)	730 (6.4)	5357 (48.7)	662 (6.1)
Grade 1	780 (6.8)	584 (5.1)	2316 (21.1)	505 (4.6)
Grade 2	253 (2.2)	138 (1.2)	2877 (26.2)	142 (1.3)
Grade 3[e]	17 (0.1)	8 (<0.1)	164 (1.5)	15 (0.1)
Grade 4[e]	0	0	0	0
Use of antipyretic or pain medication	2656 (23.3)	1523 (13.4)	6307 (57.3)	1254 (11.5)
Age ≥ 65				
	N=3760	**N=3749**	**N=3691**	**N=3649**
Any systemic AR	N1=3760	N1=3749	N1=3691	N1=3649
Any	1817 (48.3)	1334 (35.6)	2655 (71.9)	1135 (31.1)
Grade 1	1279 (34.0)	967 (25.8)	1102 (29.9)	788 (21.6)
Grade 2	454 (12.1)	304 (8.1)	1153 (31.2)	287 (7.9)
Grade 3	84 (2.2)	61 (1.6)	398 (10.8)	59 (1.6)
Grade 4	0	2 (<0.1)	2 (<0.1)	1 (<0.1)
Fever[a]	N1=3759	N1=3749	N1=3689	N1=3648
≥38.0°C	10 (0.3)	7 (0.2)	367 (9.9)	5 (0.1)
38.0°C to 38.4°C	7 (0.2)	3 (<0.1)	251 (6.8)	3 (<0.1)
38.5°C to 38.9°C	2 (<0.1)	1 (<0.1)	97 (2.6)	1 (<0.1)
39°C to 40.0°C	1 (<0.1)	1 (<0.1)	18 (0.5)	0
>40.0°C	0	2 (<0.1)	1 (<0.1)	1 (<0.1)
Headache	N1=3760	N1=3746	N1=3689	N1=3649
Any	922 (24.5)	723 (19.3)	1708 (46.3)	652 (17.9)
Grade 1	779 (20.7)	629 (16.8)	1146 (31.1)	558 (15.3)
Grade 2	90 (2.4)	60 (1.6)	455 (12.3)	61 (1.7)
Grade 3[b]	53 (1.4)	34 (0.9)	107 (2.9)	33 (0.9)
Grade 4[b]	0	0	0	0
Fatigue	N1=3760	N1=3746	N1=3689	N1=3649
Any	1251 (33.3)	852 (22.7)	2154 (58.4)	717 (19.6)
Grade 1	853 (22.7)	605 (16.2)	904 (24.5)	480 (13.2)
Grade 2	368 (9.8)	225 (6.0)	995 (27.0)	217 (5.9)
Grade 3[c]	30 (0.8)	22 (0.6)	255 (6.9)	20 (0.5)
Grade 4[c]	0	0	0	0
Myalgia	N1=3760	N1=3746	N1=3689	N1=3649
Any	742 (19.7)	444 (11.9)	1740 (47.2)	399 (10.9)
Grade 1	568 (15.1)	360 (9.6)	827 (22.4)	305 (8.4)
Grade 2	157 (4.2)	75 (2.0)	708 (19.2)	84 (2.3)
Grade 3[c]	17 (0.5)	9 (0.2)	205 (5.6)	10 (0.3)
Grade 4[c]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Arthralgia	N1=3760	N1=3746	N1=3689	N1=3649
Any	618 (16.4)	457 (12.2)	1293 (35.1)	399 (10.9)
Grade 1	474 (12.6)	367 (9.8)	698 (18.9)	302 (8.3)
Grade 2	131 (3.5)	82 (2.2)	470 (12.7)	90 (2.5)
Grade 3[c]	13 (0.3)	8 (0.2)	125 (3.4)	7 (0.2)
Grade 4[c]	0	0	0	0
Nausea/vomiting	N1=3760	N1=3746	N1=3689	N1=3649
Any	194 (5.2)	167 (4.5)	439 (11.9)	134 (3.7)
Grade 1	158 (4.2)	138 (3.7)	339 (9.2)	110 (3.0)
Grade 2	32 (0.9)	24 (0.6)	89 (2.4)	21 (0.6)
Grade 3[d]	4 (0.1)	5 (0.1)	10 (0.3)	3 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=3760	N1=3746	N1=3689	N1=3649
Any	201 (5.3)	148 (4.0)	1143 (31.0)	151 (4.1)
Grade 1	158 (4.2)	122 (3.3)	591 (16.0)	124 (3.4)
Grade 2	36 (1.0)	20 (0.5)	525 (14.2)	25 (0.7)
Grade 3[e]	7 (0.2)	6 (0.2)	27 (0.7)	2 (<0.1)
Grade 4[e]	0	0	0	0
Use of antipyretic or pain medication	673 (17.9)	477 (12.7)	1548 (41.9)	331 (9.1)

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1). Medications were collected on the eDiary.

[a] Fever is defined as: Grade 1=38 to 38.4°C; Grade 2=38.5 to 38.9°C; Grade 3=39 to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2, Table 14.1.5.5.1, Table 14.1.5.5.2.

5.2.2.2 Onset After 7 Days

Table 41: (Table V) Frequency of Delayed Solicited Systemic Reactions (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1 N=15184	Placebo Dose 1 N=15162	mRNA-1273 Dose 2 N=14731	Placebo Dose 2 N=14631
Delayed systemic reaction				
Any – n (%)	471 (3.1)	471 (3.1)	710 (4.8)	778 (5.3)
Severe – n (%)	7 (<0.1)	7 (<0.1)	26 (0.2)	18 (0.1)
Medically attended– n (%)	56 (0.4)	76 (0.5)	212 (1.4)	233 (1.6)
SAE– n (%)	1 (<0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)
Day of onset: median (min, max)	15.0 (8, 141)	15.0 (8, 128)	28.0 (8, 166)	28.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 229)	3.0 (1, 218)	5.0 (1, 201)	4.0 (1, 182)
Fever				
Any – n (%)	26 (0.2)	26 (0.2)	69 (0.5)	85 (0.6)
Severe – n (%)	0	0	1 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	21.0 (8, 39)	20.5 (8, 128)	48.0 (8, 132)	41.0 (8, 152)
Duration (days): median (min, max)	2 (1, 27)	2.0 (1, 11)	2.0 (1, 111)	3.0 (1, 152)
Headache				
Any – n (%)	195 (1.3)	223 (1.5)	361 (2.5)	411 (2.8)
Severe – n (%)	2 (<0.1)	4 (<0.1)	12 (<0.1)	8 (<0.1)
Day of onset: median (min, max)	15.0 (8, 140)	15.0 (8, 121)	29.0 (8, 145)	31.0 (8, 146)
Duration (days): median (min, max)	3.0 (1, 206)	3.0 (1, 207)	4.0 (1, 180)	4.0 (1, 170)
Fatigue				
Any– n (%)	144 (0.9)	126 (0.8)	214 (1.5)	233 (1.6)
Severe– n (%)	2 (<0.1)	1 (<0.1)	6 (<0.1)	7 (<0.1)
Day of onset: median (min, max)	15.0 (8, 141)	13.5 (8, 103)	33.0 (8, 166)	36.0 (8, 144)
Duration (days): median (min, max)	7.0 (1, 110)	6.0 (1, 174)	5.0 (1, 177)	5.0 (1, 182)
Myalgia				
Any – n (%)	96 (0.6)	82 (0.5)	163 (1.1)	197 (1.3)
Severe – n (%)	0	1 (<0.1)	4 (<0.1)	4 (<0.1)
Day of onset: median (min, max)	16.0 (8, 141)	15.0 (8, 103)	30.0 (8, 166)	30.0 (8, 135)
Duration (days): median (min, max)	6.0 (1, 229)	3.5 (1, 50)	4.0 (1, 201)	4.0 (1, 182)
Arthralgia				
Any– n (%)	79 (0.5)	77 (0.5)	101 (0.7)	87 (0.6)
Severe– n (%)	2 (<0.1)	0	6 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	17.0 (8, 35)	13.0 (8, 66)	26.0 (8, 122)	26.0 (8, 141)
Duration (days): median (min, max)	9.0 (1, 223)	10.0 (1, 218)	32.0 (1, 186)	15.0 (1, 182)
Nausea/Vomiting				
Any– n (%)	63 (0.4)	68 (0.4)	130 (0.9)	145 (1.0)
Severe– n (%)	2 (<0.1)	1 (<0.1)	7 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	19.0 (8, 141)	17.0 (8, 118)	35.5 (8, 147)	36.0 (8, 144)
Duration (days): median (min, max)	3.0 (1, 199)	3.0 (1, 123)	3.0 (1, 183)	3.0 (1, 156)

Event	mRNA-1273 Dose 1 N=15184	Placebo Dose 1 N=15162	mRNA-1273 Dose 2 N=14731	Placebo Dose 2 N=14631
Chills				
Any– n (%)	30 (0.2)	30 (0.2)	64 (0.4)	91 (0.6)
Severe– n (%)	0	0	1 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	17.0 (8, 33)	16.0 (8, 30)	37.5 (8, 139)	34.0 (8, 152)
Duration (days): median (min, max)	2.0 (1, 31)	2.0 (1, 15)	3.0 (1, 62)	3.0 (1, 120)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum; SAE=serious adverse event.

Notes: Solicited systemic AR includes fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants who received the corresponding injection (N).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.21.1.3.1, Table 14.3.1.21.1.3.2; Ad hoc Table 14.3.1.21.1.3.5.2, Ad hoc Table 14.3.1.21.1.3.6.2, Ad hoc Table 14.3.1.21.1.5.1.1, Ad hoc Table 14.3.1.21.1.5.1.2, Ad hoc Table 14.3.1.21.1.6.1.1, Ad hoc Table 14.3.1.21.1.6.1.2, Ad hoc Table 14.3.1.21.1.7.1.1, Ad hoc Table 14.3.1.21.7.1.2.

Table 42: (Table V) Frequency of Delayed Solicited Systemic Reactions, by Baseline SARS-CoV-2 Status (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Baseline SARS-CoV-2 Status Positive	**N=347**	**N=337**	**N=234**	**N=236**
Delayed systemic reaction				
Any – n (%)	13 (3.7)	12 (3.6)	8 (3.4)	9 (3.8)
Severe – n (%)	0	0	0	0
Medically attended – n (%)	2 (0.6)	1 (0.3)	2 (0.9)	2 (0.8)
SAE – n (%)	0	0	0	0
Day of onset: median (min, max)	11.0 (8, 140)	15.0 (8, 53)	21.0 (8, 86)	22.0 (9, 84)
Duration (days): median (min, max)	12.0 (1, 51)	5.0 (1, 33)	5.0 (1, 143)	4.0 (1, 9)
Fever				
Any– n (%)	1 (0.3)	0	0	0
Severe– n (%)	0	0	0	0
Day of onset: median (min, max)	9.0 (9, 9)	NA	NA	NA
Duration (days): median (min, max)	2.0 (2, 2)	NA	NA	NA
Headache				
Any – n (%)	7 (2.0)	7 (2.1)	7 (3.0)	6 (2.5)
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	11.0 (8, 140)	14.0 (8, 24)	22.0 (14, 123)	18.5 (9, 24)
Duration (days): median (min, max)	12.0 (1, 51)	1.0 (1, 26)	3.0 (1, 122)	2.5 (1, 8)
Fatigue				
Any – n (%)	3 (0.9)	2 (0.6)	2 (0.9)	4 (1.7)
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	12.0 (11, 118)	8.0 (8, 8)	26.0 (17, 35)	23.0 (12, 84)
Duration (days): median (min, max)	27.0 (8, 31)	9.5 (9, 10)	71.5 (3, 140)	7.0 (4, 9)
Myalgia				
Any – n (%)	2 (0.6)	2 (0.6)	2 (0.9)	1 (0.4)
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	10.0 (8, 12)	17.0 (8, 26)	27.5 (17, 38)	12.0 (12, 12)
Duration (days): median (min, max)	4.0 (2, 6)	5.0 (1, 9)	46.5 (1, 92)	9.0 (9, 9)
Arthralgia				
Any – n (%)	2 (0.6)	3 (0.9)	2 (0.9)	0
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	11.0 (8, 14)	17.0 (8, 53)	40.0 (26, 54)	NA
Duration (days): median (min, max)	12.5 (2, 23)	28.0 (12, 33)	72.5 (2, 143)	NA
Nausea/Vomiting				
Any – n (%)	0	0	2 (0.9)	0
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	NA	NA	91.5 (36, 147)	NA
Duration (days): median (min, max)	NA	NA	8.0 (2, 14)	NA
Chills				
Any – n (%)	0	0	2 (0.9)	1 (0.4)
Severe – n (%)	0	0	0	0
Day of onset: median (min, max)	NA	NA	23.5 (8, 39)	85.0 (85, 85)
Duration (days): median (min, max)	NA	NA	36.0 (10, 62)	8.0 (8, 8)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Baseline SARS-CoV-2 Status Negative	**N=14750**	**N=14741**	**N=14416**	**N=14316**
Delayed systemic reaction				
Any– n (%)	457 (3.1)	457 (3.1)	697 (4.8)	769 (5.4)
Severe– n (%)	7 (<0.1)	7 (<0.1)	26 (0.2)	18 (0.1)
Medically attended– n (%)	53 (0.4)	75 (0.5)	207 (1.4)	231 (1.6)
SAE– n (%)	1 (<0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)
Day of onset: median (min, max)	15.0 (8, 141)	15.0 (8, 128)	28.0 (8, 166)	28.0 (8, 152)
Duration (days): median (min, max)	4.0 (1, 229)	3.0 (1, 218)	5.0 (1, 201)	4.0 (1, 182)
Fever				
Any– n (%)	25 (0.2)	26 (0.2)	69 (0.5)	85 (0.6)
Severe– n (%)	0	0	1 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	22.0 (8, 39)	20.5 (8, 128)	48.0 (8, 132)	41.0 (8, 152)
Duration (days): median (min, max)	2.0 (1, 27)	2.0 (1, 11)	2.0 (1, 111)	3.0 (1, 152)
Headache				
Any – n (%)	188 (1.3)	216 (1.5)	350 (2.4)	405 (2.8)
Severe – n (%)	2 (<0.1)	4 (<0.1)	12 (<0.1)	8 (<0.1)
Day of onset: median (min, max)	15.0 (8, 140)	15.0 (8, 121)	29.0 (8, 145)	32.0 (8, 146)
Duration (days): median (min, max)	3.0 (1, 206)	3.0 (1, 207)	3.5 (1, 180)	4.0 (1, 170)
Fatigue				
Any– n (%)	141 (1.0)	124 (0.8)	210 (1.5)	229 (1.6)
Severe– n (%)	2 (<0.1)	1 (<0.1)	6 (<0.1)	7 (<0.1)
Day of onset: median (min, max)	15.0 (8, 141)	14.0 (8, 103)	33.0 (8, 166)	36.0 (8, 144)
Duration (days): median (min, max)	7.0 (1, 110)	5.5 (1, 174)	5.0 (1, 177)	5.0 (1, 182)
Myalgia				
Any– n (%)	93 (0.6)	79 (0.5)	160 (1.1)	196 (1.4)
Severe– n (%)	0	1 (<0.1)	4 (<0.1)	4 (<0.1)
Day of onset: median (min, max)	16.0 (8, 141)	15.0 (8, 103)	29.5 (8, 166)	30.5 (8, 135)
Duration (days): median (min, max)	7.0 (1, 229)	3.0 (1, 50)	4.0 (1, 201)	4.0 (1, 182)
Arthralgia				
Any– n (%)	77 (0.5)	73 (0.5)	99 (0.7)	87 (0.6)
Severe– n (%)	2 (<0.1)	0	6 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	17.0 (8, 35)	13.0 (8, 66)	26.0 (8, 122)	26.0 (8, 141)
Duration (days): median (min, max)	9.0 (1, 223)	10.0 (1, 218)	32.0 (1, 186)	15.0 (1, 182)
Nausea/Vomiting				
Any– n (%)	63 (0.4)	67 (0.5)	128 (0.9)	145 (1.0)
Severe– n (%)	2 (<0.1)	1 (<0.1)	7 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	19.0 (8, 141)	17.0 (8, 118)	35.0 (8, 138)	36.0 (8, 144)
Duration (days): median (min, max)	3.0 (1, 199)	3.0 (1, 123)	3.0 (1, 183)	3.0 (1, 156)
Chills				
Any– n (%)	30 (0.2)	30 (0.2)	62 (0.4)	90 (0.6)
Severe– n (%)	0	0	1 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	17.0 (8, 33)	16.0 (8, 30)	37.5 (8, 139)	34.0 (8, 152)
Duration (days): median (min, max)	2.0 (1, 31)	2.0 (1, 15)	3.0 (1, 56)	3.0 (1, 120)

Abbreviations: IP=investigational product; max=maximum; min=minimum; NA=not applicable; SAE=serious adverse event.

Notes: Solicited systemic adverse reactions include fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants who received the corresponding injection (N).

Source: Ad hoc Table 14.3.1.21.1.3.5.3, Ad hoc Table 14.3.1.21.1.3.6.3, Ad hoc Table 14.3.1.21.1.5.2.1, Ad hoc Table 14.2.1.21.1.5.2.2, Ad hoc Table 14.3.1.21.1.6.2.1, Ad hoc Table 14.3.1.21.1.6.2.2, Ad hoc Table 14.3.1.21.1.7.2.1, Ad hoc Table 14.3.1.21.1.7.2.2.

Table 43: (Table V) Frequency of Delayed Solicited Systemic Reactions, by Age Group (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Age 18 to < 65	**N=11415**	**N=11411**	**N=11027**	**N=10964**
Delayed systemic reaction				
Any – n (%)	365 (3.2)	388 (3.4)	541 (4.9)	599 (5.5)
Severe – n (%)	4 (<0.1)	5 (<0.1)	20 (0.2)	14 (0.1)
Medically attended– n (%)	40 (0.4)	62 (0.5)	167 (1.5)	181 (1.7)
SAE– n (%)	0	2 (<0.1)	2 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	15.0 (8, 140)	15.0 (8, 103)	30.0 (8, 145)	28.0 (8, 152)
Duration (days): median (min, max)	3.0 (1, 223)	3.0 (1, 218)	5.0 (1, 201)	4.0 (1, 182)
Fever				
Any– n (%)	18 (0.2)	21 (0.2)	51 (0.5)	68 (0.6)
Severe– n (%)	0	0	0	1 (<0.1)
Day of onset: median (min, max)	21.0 (8, 39)	21.0 (8, 90)	51.0 (8, 132)	41.5 (8, 152)
Duration (days): median (min, max)	2.0 (1, 27)	2.0 (1, 11)	2.0 (1, 111)	3.0 (1, 152)
Headache				
Any – n (%)	162 (1.4)	189 (1.7)	297 (2.7)	338 (3.1)
Severe – n (%)	2 (<0.1)	3 (<0.1)	11 (<0.1)	8 (<0.1)
Day of onset: median (min, max)	15.0 (8, 140)	16.0 (8, 105)	33.0 (8, 145)	31.0 (8, 146)
Duration (days): median (min, max)	2.0 (1, 206)	2.0 (1, 207)	3.0 (1, 180)	4.0 (1, 170)
Fatigue				
Any – n (%)	113 (1.0)	110 (1.0)	153 (1.4)	186 (1.7)
Severe – n (%)	2 (<0.1)	1 (<0.1)	4 (<0.1)	6 (<0.1)
Day of onset: median (min, max)	16.0 (8, 140)	14.5 (8, 103)	38.0 (8, 145)	36.0 (8, 144)
Duration (days): median (min, max)	8.0 (1, 110)	6.0 (1, 174)	5.0 (1, 177)	5.0 (1, 182)
Myalgia				
Any – n (%)	73 (0.6)	64 (0.6)	128 (1.2)	155 (1.4)
Severe – n (%)	0	1 (<0.1)	4 (<0.1)	3 (<0.1)
Day of onset: median (min, max)	16.0 (8, 140)	18.5 (8, 103)	29.0 (8, 130)	32.0 (8, 135)
Duration (days): median (min, max)	6.0 (1, 175)	3.0 (1, 38)	4.0 (1, 201)	4.0 (1, 152)
Arthralgia				
Any – n (%)	57 (0.5)	56 (0.5)	75 (0.7)	56 (0.5)
Severe – n (%)	0	0	3 (<0.1)	0
Day of onset: median (min, max)	17.0 (8, 35)	12.0 (8, 44)	28.0 (8, 122)	28.5 (8, 138)
Duration (days): median (min, max)	10.0 (1, 223)	10.0 (1, 218)	30.0 (1, 186)	14.5 (1, 173)
Nausea/Vomiting				
Any – n (%)	47 (0.4)	56 (0.5)	99 (0.9)	110 (1.0)
Severe – n (%)	1 (<0.1)	0	7 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	19.0 (8, 141)	17.5 (8, 104)	41.0 (8, 147)	37.0 (8, 144)
Duration (days): median (min, max)	3.0 (1, 199)	3.0 (1, 123)	3.0 (1, 183)	3.0 (1, 121)
Chills				
Any – n (%)	23 (0.2)	22 (0.2)	47 (0.4)	68 (0.6)
Severe – n (%)	0	0	1 (<0.1)	2 (<0.1)
Day of onset: median (min, max)	19.0 (8, 33)	19.5 (8, 30)	35.0 (8, 139)	37.5 (8,152)
Duration (days): median (min, max)	2.0 (1, 11)	2.0 (1, 15)	3.0 (1, 62)	3.0 (1, 120)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Age ≥ 65	**N=3769**	**N=3751**	**N=3704**	**N=3667**
Delayed systemic reaction				
Any– n (%)	106 (2.8)	83 (2.2)	169 (4.6)	179 (4.9)
Severe– n (%)	3 (<0.1)	2 (<0.1)	6 (0.2)	4 (0.1)
Medically attended– n (%)	16 (0.4)	14 (0.4)	45 (1.2)	52 (1.4)
SAE– n (%)	1 (<0.1)	0	0	2 (<0.1)
Day of onset: median (min, max)	15.0 (8, 141)	13.0 (8, 128)	22.0 (8, 166)	28.0 (8, 141)
Duration (days): median (min, max)	4.0 (1, 229)	4.0 (1, 215)	5.0 (1, 183)	4.0 (1, 182)
Fever				
Any– n (%)	8 (0.2)	5 (0.1)	18 (0.5)	17 (0.5)
Severe– n (%)	0	0	1 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	17.0 (9, 30)	17.0 (8, 128)	42.5 (10. 75)	33.0 (9, 135)
Duration (days): median (min, max)	2.5 (1, 8)	4.0 (2, 8)	2.0 (1, 8)	2.0 (1, 7)
Headache				
Any – n (%)	33 (0.9)	34 (0.9)	64 (1.7)	73 (2.0)
Severe – n (%)	0	1 (<0.1)	1 (<0.1)	0
Day of onset: median (min, max)	15.0 (8, 89)	12.5 (8, 121)	20.0 (8, 134)	33.0 (8, 127)
Duration (days): median (min, max)	3.0 (1, 176)	4.5 (1, 83)	4.5 (1, 158)	4.0 (1, 166)
Fatigue				
Any– n (%)	31 (0.8)	16 (0.4)	61 (1.6)	47 (1.3)
Severe– n (%)	0	0	2 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	11.0 (8, 141)	10.5 (8, 32)	25.0 (8, 166)	34.0 (8, 141)
Duration (days): median (min, max)	5.0 (1, 65)	5.5 (1, 28)	5.0 (1, 177)	4.0 (1, 162)
Myalgia				
Any– n (%)	23 (0.6)	18 (0.5)	35 (0.9)	42 (1.1)
Severe– n (%)	0	0	0	1 (<0.1)
Day of onset: median (min, max)	16.0 (8, 141)	8.5 (8, 23)	32.0 (8,166)	22.0 (8, 134)
Duration (days): median (min, max)	8.0 (1, 229)	4.5 (1, 50)	4.0 (1, 115)	4.0 (1, 182)
Arthralgia				
Any– n (%)	22 (0.6)	21 (0.6)	26 (0.7)	31 (0.8)
Severe– n (%)	2 (<0.1)	0	3 (<0.1)	1 (<0.1)
Day of onset: median (min, max)	16.0 (8, 35)	13.0 (8, 66)	21.0 (8, 94)	25.0 (8, 141)
Duration (days): median (min, max)	9.0 (1, 216)	16.0 (1, 215)	38.0 (1, 183)	29.0 (1, 182)
Nausea/Vomiting				
Any– n (%)	16 (0.4)	12 (0.3)	31 (0.8)	35 (1.0)
Severe– n (%)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Day of onset: median (min, max)	18.5 (8, 55)	17.0 (8, 118)	24.0 (9, 81)	33.0 (8, 121)
Duration (days): median (min, max)	2.5 (1, 96)	3.0 (1, 28)	2.0 (1, 26)	3.0 (1, 156)
Chills				
Any– n (%)	7 (0.2)	8 (0.2)	17 (0.5)	23 (0.6)
Severe– n (%)	0	0	0	0
Day of onset: median (min, max)	15.0 (8, 32)	11.0 (8, 24)	47.0 (10, 105)	28.0 (8, 134)
Duration (days): median (min, max)	1.0 (1, 31)	2.5 (1, 8)	3.0 (1, 13)	2.0 (1, 15)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum; SAE=serious adverse event.

Notes: Solicited systemic AR includes fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Any=Grade 1 or higher. The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants who received the corresponding injection (N).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.21.1.3.1, 14.3.1.21.1.3.2; Ad hoc Table 14.3.1.21.1.3.5.4, Ad hoc Table 14.3.1.21.1.3.6.4, Ad hoc Table 14.3.1.21.1.5.3.1, Ad hoc Table 14.3.1.21.1.5.3.2, Ad hoc Table 14.3.1.21.1.6.3.1, Ad hoc Table 14.3.1.21.1.6.3.2, Ad hoc Table 14.3.1.21.1.7.3.1, Ad hoc Table 14.3.1.21.1.7.3.2.

5.2.2.3 Overall Characteristics

Table 44: (Table X) Characteristics of Solicited Systemic Adverse Reactions (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Any systemic adverse reaction – n/N1 (%)	8316/15166 (54.8)	6397/15151 (42.2)	11678/14690 (79.5)	5343/14577 (36.7)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 193)	2.0 (1, 188)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	861/15166 (5.7)	841/15151 (5.6)	838/14690 (5.7)	717/14577 (4.9)
Fever – n/N1 (%)	112/15163 (0.7)	44/15149 (0.3)	2276/14682 (15.5)	43/14573 (0.3)
Day of onset: median (min, max)	2.0 (1, 7)	4.0 (1, 7)	2.0 (1, 7)	4.0 (1, 7)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 3)	1.0 (1, 9)	1.0 (1, 11)
Persisted beyond 7 days, n/N1 (%)	4/15163 (<0.1)	3/15149 (<0.1)	2/14682 (<0.1)	1/14573 (<0.1)
Headache– n/N1 (%)	4950/15162 (32.6)	4026/15146 (26.6)	8637/14687 (58.8)	3427/14575 (23.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 46)	1.0 (1, 85)	2.0 (1, 196)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	336/15162 (2.2)	303/15146 (2.0)	388/14687 (2.6)	304/14575 (2.1)
Fatigue – n/N1 (%)	5636/15162 (37.2)	4133/15146 (27.3)	9607/14687 (65.4)	3418/14575 (23.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	2.0 (1, 92)	2.0 (1, 131)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	511/15162 (3.4)	462/15146 (3.1)	487/14687 (3.3)	397/14575 (2.7)
Myalgia – n/N1 (%)	3442/15162 (22.7)	2069/15146 (13.7)	8529/14687 (58.1)	1824/14575 (12.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 74)	1.0 (1, 53)	1.0 (1, 170)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	223/15162 (1.5)	243/15146 (1.6)	240/14687 (1.6)	231/14575 (1.6)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Arthralgia – n/N1 (%)	2510/15162 (16.6)	1784/15146 (11.8)	6303/14687 (42.9)	1579/14575 (10.8)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 193)	2.0 (1, 188)	1.0 (1, 185)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	244/15162 (1.6)	278/15146 (1.8)	270/14687 (1.8)	264/14575 (1.8)
Nausea/vomiting – n/N1 (%)	1262/15162 (8.3)	1075/15146 (7.1)	2794/14687 (19.0)	941/14575 (6.5)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 24)	1.0 (1, 35)	1.0 (1, 176)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	61/15162 (0.4)	65/15146 (0.4)	59/14687 (0.4)	48/14575 (0.3)
Chills – n/N1 (%)	1251/15162 (8.3)	878/15146 (5.8)	6500/14687 (44.3)	813/14575 (5.6)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 28)	1.0 (1, 35)	1.0 (1, 158)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	32/15162 (0.2)	45/15146 (0.3)	53/14687 (0.4)	50/14575 (0.3)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.3.1.4.1.1, Table 14.3.1.4.1.2, Table 14.3.1.6.1.1, Table 14.3.1.6.1.2; Ad hoc Table 14.3.1.6.3.1, Ad hoc Table 14.3.1.3.6.3.2.

Table 45: (Table X) Characteristics of Solicited Systemic Adverse Reactions, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Baseline SARS-CoV-2 Status Positive				
Any systemic adverse reaction – n/N1 (%)	214/346 (61.8)	122/337 (36.2)	152/232 (65.5)	73/233 (31.3)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 6)	1.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 33)	2.0 (1, 32)	2.0 (1, 63)	2.0 (1, 153)
Persisted beyond 7 days, n/N1 (%)	17/346 (4.9)	22/337 (6.5)	8/232 (3.4)	15/233 (6.4)
Fever – n/N1 (%)	33/346 (9.5)	6/336 (1.8)	31/232 (13.4)	1/232 (0.4)
Day of onset: median (min, max)	2.0 (1, 5)	3.0 (2, 5)	2.0 (1, 4)	6.0 (6, 6)
Duration: median (min, max)	1.0 (1, 2)	1.0 (1, 2)	1.0 (1, 2)	1.0 (1, 1)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	0	0	0
Headache – n/N1 (%)	134/346 (38.7)	83/337 (24.6)	98/232 (42.2)	43/232 (18.5)
Day of onset: median (min, max)	2.0 (1, 6)	2.0 (1, 7)	2.0 (1, 6)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 21)	1.0 (1, 15)	1.5 (1, 33)	2.0 (1, 15)
Persisted beyond 7 days, n/N1 (%)	12/346 (3.5)	10/337 (3.0)	6/232 (2.6)	5/232 (2.2)
Fatigue – n/N1 (%)	138/346 (39.9)	72/337 (21.4)	106/232 (45.7)	54/232 (23.3)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 3)	2.0 (1, 6)
Duration: median (min, max)	2.0 (1, 30)	2.0 (1, 15)	2.0 (1, 13)	2.0 (1, 25)
Persisted beyond 7 days, n/N1 (%)	9/346 (2.6)	14/337 (4.2)	4/232 (1.7)	8/232 (3.4)
Myalgia – n/N1 (%)	128/346 (37.0)	47/337 (13.9)	117/232 (50.4)	34/232 (14.7)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 6)	3.0 (1, 7)
Duration: median (min, max)	1.0 (1, 33)	2.0 (1, 18)	1.0 (1, 63)	2.0 (1, 153)
Persisted beyond 7 days, n/N1 (%)	6/346 (1.7)	11/337 (3.3)	3/232 (1.3)	6/232 (2.6)
Arthralgia – n/N1 (%)	88/346 (25.4)	40/337 (11.9)	77/232 (33.2)	26/232 (11.2)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 6)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 11)	2.0 (1, 32)	2.0 (1, 53)	2.0 (1, 24)
Persisted beyond 7 days, n/N1 (%)	3/346 (0.9)	8/337 (2.4)	3/232 (1.3)	8/232 (3.4)
Nausea/vomiting – n/N1 (%)	43/346 (12.4)	25/337 (7.4)	33/232 (14.2)	13/232 (5.6)
Day of onset: median (min, max)	2.0 (1, 7)	4.0 (1, 7)	2.0 (1, 6)	3.0 (2, 7)
Duration: median (min, max)	1.0 (1, 13)	1.0 (1, 6)	1.0 (1, 6)	1.0 (1, 3)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	1/337 (0.3)	0	0

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Chills – n/N1 (%)	81/346 (23.4)	27/337 (8.0)	80/232 (34.5)	19/232 (8.2)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 6)	3.0 (1, 7)
Duration: median (min, max)	1.0 (1, 10)	1.0 (1, 6)	1.0 (1, 5)	1.0 (1, 11)
Persisted beyond 7 days, n/N1 (%)	1/346 (0.3)	3/337 (0.9)	0	3/232 (1.3)
Baseline SARS-CoV-2 Status Negative				
Any systemic adverse reaction – n/N1 (%)	8053/14733 (54.7)	6239/14730 (42.4)	11459/14377 (79.7)	5241/14266 (36.7)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 193)	2.0 (1, 188)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	837/14733 (5.7)	814/14730 (5.5)	826/14377 (5.7)	698/14266 (4.9)
Fever – n/N1 (%)	78/14731 (0.5)	38/14729 (0.3)	2235/14370 (15.6)	42/14263 (0.3)
Day of onset: median (min, max)	2.0 (1, 7)	4.0 (1, 7)	2.0 (1, 7)	3.5 (1, 7)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 3)	1.0 (1, 9)	1.0 (1, 11)
Persisted beyond 7 days, n/N1 (%)	3/14731 (<0.1)	3/14729 (<0.1)	2/14370 (<0.1)	1/14363 (<0.1)
Headache – n/N1 (%)	4787/14729 (32.5)	3917/14725 (26.6)	8488/14374 (59.1)	3363/14265 (23.6)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 46)	1.0 (1, 85)	2.0 (1, 196)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	324/14729 (2.2)	290/14725 (2.0)	381/14374 (2.7)	296/14365 (2.1)
Fatigue – n/N1 (%)	5466/14729 (37.1)	4038/14725 (27.4)	9446/14374 (65.7)	3344/14265 (23.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	2.0 (1, 92)	2.0 (1, 131)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	496/14729 (3.4)	444/14725 (3.0)	481/14374 (3.3)	386/14265 (2.7)
Myalgia – n/N1 (%)	3295/14729 (22.4)	2011/14725 (13.7)	8357/14374 (58.1)	1775/14265 (12.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 74)	1.0 (1, 53)	1.0 (1, 170)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	216/14729 (1.5)	230/14725 (1.6)	235/14374 (1.6)	224/14365 (1.6)
Arthralgia – n/N1 (%)	2406/14729 (16.3)	1735/14725 (11.8)	6181/14374 (43.0)	1543/14265 (10.8)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 193)	2.0 (1, 188)	1.0 (1, 185)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	240/14729 (1.6)	268/14725 (1.8)	266/14374 (1.9)	255/14365 (1.8)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Nausea/vomiting – n/N1 (%)	1210/14729 (8.2)	1044/14725 (7.1)	2741/14374 (19.1)	922/14265 (6.5)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 24)	1.0 (1, 35)	1.0 (1, 176)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	59/14729 (0.4)	64/14725 (0.4)	59/14374 (0.4)	48/14265 (0.3)
Chills – n/N1 (%)	1162/14729 (7.9)	846/14725 (5.7)	6384/14374 (44.4)	790/14265 (5.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 28)	1.0 (1, 35)	1.0 (1, 158)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	31/14729 (0.2)	42/14725 (0.3)	53/14374 (0.4)	47/14265 (0.3)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2, Table 14.3.1.4.3.1, Table 14.3.1.4.3.2, Table 14.3.1.6.3.1, Table 14.3.1.6.3.2; Ad hoc Table 14.3.1.3.6.4.1, Ad hoc Table 14.3.1.3.6.4.2.

Table 46: (Table X) Characteristics of Solicited Systemic Adverse Reactions, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Age 18 to < 65				
Any systemic adverse reaction – n/N1 (%)	6499/11406 (57.0)	5063/11402 (44.4)	9023/10999 (82.0)	4208/10928 (38.5)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 193)	2.0 (1, 101)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	657/11406 (5.8)	650/11402 (5.7)	644/10999 (5.9)	545/10928 (5.0)
Fever – n/N1 (%)	102/11404 (0.9)	37/11400 (0.3)	1909/10993 (17.4)	38/10925 (0.3)
Day of onset: median (min, max)	2.0 (1, 7)	4.0 (1, 7)	2.0 (1, 7)	4.0 (1, 7)
Duration: median (min, max)	1.0 (1, 8)	1.0 (1, 3)	1.0 (1, 9)	1.0 (1, 11)
Persisted beyond 7 days, n/N1 (%)	4/11404 (<0.1)	3/11400 (<0.1)	2/10993 (<0.1)	1/10925 (<0.1)
Headache – n/N1 (%)	4028/11402 (35.3)	3303/11400 (29.0)	6929/10998 (63.0)	2775/10926 (25.4)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 46)	1.0 (1, 85)	2.0 (1, 176)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	280/11402 (2.5)	247/11400 (2.2)	331/10998 (3.0)	248/10926 (2.3)
Fatigue – n/N1 (%)	4385/11402 (38.5)	3281/11400 (28.8)	7453/10998 (67.8)	2701/10926 (24.7)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	2.0 (1, 56)	2.0 (1, 50)	2.0 (1, 198)	2.0 (1, 204)
Persisted beyond 7 days, n/N1 (%)	380/11402 (3.3)	358/11400 (3.1)	375/10998 (3.4)	304/10926 (2.8)
Myalgia – n/N1 (%)	2700/11402 (23.7)	1625/11400 (14.3)	6789/10998 (61.7)	1425/10926 (13.0)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 49)	1.0 (1, 35)	2.0 (1, 170)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	161/11402 (1.4)	172/11400 (1.5)	179/10998 (1.6)	178/10926 (1.6)
Arthralgia – n/N1 (%)	1892/11402 (16.6)	1327/11400 (11.6)	5010/10998 (45.6)	1180/10926 (10.8)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 193)	2.0 (1, 101)	1.0 (1, 185)	2.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	163/11402 (1.4)	189/11400 (1.7)	196/10998 (1.8)	188/10926 (1.7)
Nausea/vomiting – n/N1 (%)	1068/11402 (9.4)	908/11400 (8.0)	2355/10998 (21.4)	807/10926 (7.4)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 24)	1.0 (1, 35)	1.0 (1, 176)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	51/11402 (0.4)	55/11400 (0.5)	52/10998 (0.5)	42/10926 (0.4)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Chills – n/N1 (%)	1050/11402 (9.2)	730/11400 (6.4)	5357/10998 (48.7)	662/10926 (6.1)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 28)	1.0 (1, 35)	1.0 (1, 29)	1.0 (1, 169)
Persisted beyond 7 days, n/N1 (%)	27/11402 (0.2)	38/11400 (0.3)	43/10998 (0.4)	38/10926 (0.3)
Age ≥ 65				
Any systemic adverse reaction – n/N1 (%)	1817/3760 (48.3)	1334/3749 (35.6)	2655/3691 (71.9)	1135/3649 (31.1)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration (days): median (min, max)	2.0 (1, 169)	2.0 (1, 188)	2.0 (1, 196)	2.0 (1, 146)
Persisted beyond 7 days, n/N1 (%)	204/3760 (5.4)	191/3749 (5.1)	194/3691 (5.3)	172/3649 (4.7)
Fever – n/N1 (%)	10/3759 (0.3)	7/3749 (0.2)	367/3689 (9.9)	5/3648 (0.1)
Day of onset: median (min, max)	4.0 (1, 6)	1.0 (1, 7)	2.0 (1, 6)	3.0 (2, 6)
Duration: median (min, max)	1.0 (1, 2)	1.0 (1, 3)	1.0 (1, 3)	1.0 (1, 2)
Persisted beyond 7 days, n/N1 (%)	0	0	0	0
Headache – n/N1 (%)	922/3760 (24.5)	723/3746 (19.3)	1708/3689 (46.3)	652/3649 (17.9)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 41)	1.0 (1, 30)	1.0 (1, 196)	1.0 (1, 89)
Persisted beyond 7 days, n/N1 (%)	56/3760 (1.5)	56/3746 (1.5)	57/3689 (1.5)	56/3649 (1.5)
Fatigue – n/N1 (%)	1251/3760 (33.3)	852/3746 (22.7)	2154/3689 (58.4)	717/3649 (19.6)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	2.0 (1, 92)	2.0 (1, 131)	2.0 (1, 172)	2.0 (1, 146)
Persisted beyond 7 days, n/N1 (%)	131/3760 (3.5)	104/3746 (2.8)	112/3689 (3.0)	93/3649 (2.5)
Myalgia – n/N1 (%)	742/3760 (19.7)	444/3746 (11.9)	1740/3689 (47.2)	399/3649 (10.9)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 74)	1.0 (1, 53)	1.0 (1, 162)	2.0 (1, 146)
Persisted beyond 7 days, n/N1 (%)	62/3760 (1.6)	71/3746 (1.9)	61/3689 (1.7)	53/3649 (1.5)
Arthralgia – n/N1 (%)	618/3760 (16.4)	457/3746 (12.2)	1293/3689 (35.1)	399/3649 (10.9)
Day of onset: median (min, max)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 169)	2.0 (1, 188)	1.0 (1, 162)	2.0 (1, 146)
Persisted beyond 7 days, n/N1 (%)	81/3760 (2.2)	89/3746 (2.4)	74/3689 (2.0)	76/3649 (2.1)

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Nausea/vomiting – n/N1 (%)	194/3760 (5.2)	167/3746 (4.5)	439/3689 (11.9)	134/3649 (3.7)
Day of onset: median (min, max)	3.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)	3.0 (1, 7)
Duration: median (min, max)	1.0 (1, 11)	1.0 (1, 11)	1.0 (1, 29)	1.0 (1, 10)
Persisted beyond 7 days, n/N1 (%)	10/3760 (0.3)	10/3746 (0.3)	7/3689 (0.2)	6/3649 (0.2)
Chills – n/N1 (%)	201/3760 (5.3)	148/3746 (4.0)	1143/3689 (31.0)	151/3649 (4.1)
Day of onset: median (min, max)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: median (min, max)	1.0 (1, 17)	1.0 (1, 11)	1.0 (1, 158)	1.0 (1, 27)
Persisted beyond 7 days, n/N1 (%)	5/3760 (0.1)	7/3746 (0.2)	10/3689 (0.3)	12/3649 (0.3)

Abbreviations: AR=adverse reaction; IP=investigational product; max=maximum; min=minimum.

Notes: The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consists of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of the first (second) study injection through the following 6 days. Duration (number of days) is calculated as the days of the solicited AR reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days were included. Percentages are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2, Table 14.3.1.4.2.1, Table 14.3.1.4.2.2, Table 14.3.1.6.2.1, Table 14.3.1.6.2.2; Ad hoc Table 14.3.1.3.6.5.1, Ad hoc Table 14.3.1.3.6.5.2.

5.3 Unsolicited Adverse Events

5.3.1 Overall Adverse Events

Table 47: (Table Y) Frequency of Unsolicited Adverse Events with Occurrence in ≥1% of Participants in Any Treatment Group up to 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set)

	mRNA-1273 (N=15184)		Placebo (N=15162)	
Primary System Organ Class Preferred Term	**Any n (%)**	**Severe n (%)**	**Any n (%)**	**Severe n (%)**
Infections and infestations				
Adverse events in any PT[a]	783 (5.2)	20 (0.1)	952 (6.3)	34 (0.2)
COVID-19	22 (0.1)	0	156 (1.0)	7 (<0.1)
Blood and lymphatic system disorders				
Adverse events in any PT[a]	292 (1.9)	3 (<0.1)	148 (1.0)	0
Lymphadenopathy	264 (1.7)	1 (<0.1)	127 (0.8)	0
Nervous system disorders				
Adverse events in any PT[a]	1008 (6.6)	26 (0.2)	881 (5.8)	23 (0.2)
Headache	744 (4.9)	14 (<0.1)	687 (4.5)	11 (<0.1)
Vascular disorders				
Adverse events in any PT[a]	198 (1.3)	33 (0.2)	204 (1.3)	44 (0.3)
Hypertension	153 (1.0)	28 (0.2)	161 (1.1)	34 (0.2)
Respiratory, thoracic and mediastinal disorders				
Adverse events in any PT[a]	603 (4.0)	15 (<0.1)	667 (4.4)	12 (<0.1)
Cough	177 (1.2)	3 (<0.1)	165 (1.1)	1 (<0.1)
Oropharyngeal pain	158 (1.0)	0	232 (1.5)	2 (<0.1)
Nasal congestion	155 (1.0)	2 (<0.1)	165 (1.1)	0
Rhinorrhoea	130 (0.9)	2 (<0.1)	145 (1.0)	0
Gastrointestinal disorders				
Adverse events in any PT[a]	599 (3.9)	21 (0.1)	567 (3.7)	16 (0.1)
Diarrhoea	204 (1.3)	3 (<0.1)	199 (1.3)	1 (<0.1)
Nausea	162 (1.1)	5 (<0.1)	164 (1.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders				
Adverse events in any PT[a]	1007 (6.6)	26 (0.2)	1017 (6.7)	35 (0.2)
Arthralgia	391 (2.6)	7 (<0.1)	389 (2.6)	7 (<0.1)
Myalgia	387 (2.5)	9 (<0.1)	388 (2.6)	4 (<0.1)
General disorders and administration site conditions				
Adverse events in any PT[a]	1606 (10.6)	55 (0.4)	1065 (7.0)	20 (0.1)
Fatigue	752 (5.0)	20 (0.1)	666 (4.4)	9 (<0.1)
Injection site pain	258 (1.7)	4 (<0.1)	118 (0.8)	1 (<0.1)
Injection site erythema	157 (1.0)	8 (<0.1)	39 (0.3)	0

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SOC=system organ class; TEAE=treatment-emergent adverse event.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety participants.

[a] Participant experienced at least 1 TEAE within the SOC regardless of the MedDRA PT.
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.8.1.1, Table 14.3.1.17.1.1.

5.3.2 Serious Adverse Events

5.3.2.1 Overall Serious Adverse Events

Table 48: (Table Z) Percentage of Participants Reporting Serious Adverse Events up to 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number (%) of participants reporting serious adverse events		98 (0.6)	104 (0.7)
Infections and infestations	Adverse events in any PT	13 (<0.1)	19 (0.1)
	Pneumonia	3 (<0.1)	4 (<0.1)
	Appendicitis	1 (<0.1)	3 (<0.1)
	COVID-19	1 (<0.1)	4 (<0.1)
	Cellulitis	1 (<0.1)	0
	Clostridium difficile infection	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia mycoplasmal	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	1 (<0.1)
	Toxic shock syndrome	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	COVID-19 pneumonia	0	1 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Diverticulitis	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Sepsis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)
	Urinary tract infection	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	9 (<0.1)	8 (<0.1)
	Prostate cancer	3 (<0.1)	3 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	0
	Pelvic neoplasm	1 (<0.1)	0
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Lung adenocarcinoma	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Blood loss anaemia	1 (<0.1)	0
	Anaemia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	2 (<0.1)	4 (<0.1)
	Dehydration	2 (<0.1)	2 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
	Hypokalaemia	0	1 (<0.1)
	Hyponatraemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	5 (<0.1)	7 (<0.1)
	Alcohol withdrawal syndrome	1 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Drug abuse	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Suicidal ideation	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Confusional state	0	1 (<0.1)
	Depression	0	2 (<0.1)
	Major depression	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Nervous system disorders	Adverse events in any PT	10 (<0.1)	8 (<0.1)
	Cerebrovascular accident	2 (<0.1)	0
	Subarachnoid haemorrhage	2 (<0.1)	0
	Syncope	2 (<0.1)	2 (<0.1)
	Autonomic nervous system imbalance	1 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Embolic stroke	1 (<0.1)	0
	Seizure	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	14 (<0.1)	17 (0.1)
	Atrial fibrillation	3 (<0.1)	3 (<0.1)
	Cardiac failure congestive	3 (<0.1)	3 (<0.1)
	Myocardial infarction	3 (<0.1)	1 (<0.1)
	Acute myocardial infarction	2 (<0.1)	1 (<0.1)
	Acute coronary syndrome	1 (<0.1)	0
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Atrial flutter	1 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)
	Coronary artery disease	1 (<0.1)	2 (<0.1)
	Cardiac failure	0	2 (<0.1)
	Pericardial effusion	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	4 (<0.1)	8 (<0.1)
	Hypertension	2 (<0.1)	1 (<0.1)
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Hypertensive urgency	1 (<0.1)	1 (<0.1)
	Hypotension	1 (<0.1)	1 (<0.1)
	Aortic stenosis	0	1 (<0.1)
	Fibromuscular dysplasia	0	1 (<0.1)
	Hypertensive emergency	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	9 (<0.1)	15 (<0.1)
	Pulmonary embolism	3 (<0.1)	3 (<0.1)
	Acute respiratory failure	2 (<0.1)	3 (<0.1)
	Respiratory failure	2 (<0.1)	0
	Atelectasis	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pleural effusion	1 (<0.1)	1 (<0.1)
	Chronic obstructive pulmonary disease	0	3 (<0.1)
	Emphysema	0	1 (<0.1)
	Hypoxia	0	1 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	15 (<0.1)	7 (<0.1)
	Colitis	2 (<0.1)	1 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Nausea	2 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Inguinal hernia	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Vomiting	1 (<0.1)	1 (<0.1)
	Abdominal pain	0	2 (<0.1)
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
	Gastritis	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	3 (<0.1)	0
	Cholecystitis	2 (<0.1)	0
	Bile duct stone	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	9 (<0.1)	12 (<0.1)
	Osteoarthritis	2 (<0.1)	6 (<0.1)
	Spinal stenosis	2 (<0.1)	1 (<0.1)
	Back pain	1 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)
	Musculoskeletal chest pain	1 (<0.1)	0
	Rheumatoid arthritis	1 (<0.1)	0
	Cervical spinal stenosis	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
	Spinal osteoarthritis	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	5 (<0.1)	2 (<0.1)
	Nephrolithiasis	3 (<0.1)	0
	Acute kidney injury	1 (<0.1)	1 (<0.1)
	Chronic kidney disease	1 (<0.1)	0
	Urinary retention	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	3 (<0.1)	1 (<0.1)
	Benign prostatic hyperplasia	1 (<0.1)	0
	Ovarian cyst	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (<0.1)	5 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Chest pain	1 (<0.1)	1 (<0.1)
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Feeling hot	0	1 (<0.1)
	Incarcerated hernia	0	2 (<0.1)

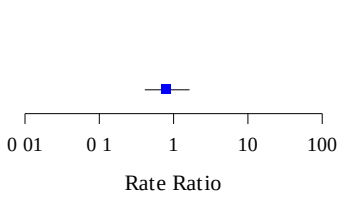
Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Injury, poisoning, and procedural complications	Adverse events in any PT	10 (<0.1)	11 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Road traffic accident	2 (<0.1)	0
	Back injury	1 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Fall	1 (<0.1)	1 (<0.1)
	Femoral neck fracture	1 (<0.1)	0
	Hip fracture	1 (<0.1)	2 (<0.1)
	Overdose	1 (<0.1)	0
	Skin laceration	1 (<0.1)	0
	Subdural haematoma	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Cartilage injury	0	1 (<0.1)
	Femur fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Joint injury	0	1 (<0.1)
	Post procedural haematoma	0	1 (<0.1)
	Post procedural haemorrhage	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

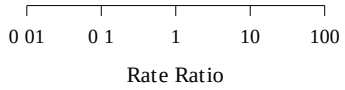
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.1.1.

Figure 2: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class up to 28 Days after Any Injection (Safety Set)

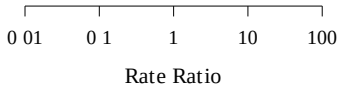


System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Infections and infestations	19 (0.1)	13 (<0.1)	0.68 (0.34, 1.36)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)	1.00 (0.10, 9.56)
Immune system disorders	1 (<0.1)	0	
Endocrine disorders	0	1 (<0.1)	
Metabolism and nutrition disorders	4 (<0.1)	2 (<0.1)	0.50 (0.11, 2.33)
Psychiatric disorders	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)
Nervous system disorders	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)
Eye disorders	1 (<0.1)	0	
Cardiac disorders	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.64)

System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Vascular disorders	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)
Respiratory, thoracic and mediastinal disorders	15 (<0.1)	9 (<0.1)	0.60 (0.27, 1.34)
Gastrointestinal disorders	7 (<0.1)	15 (<0.1)	2.14 (0.90, 5.10)
Hepatobiliary disorders	0	3 (<0.1)	
Skin and subcutaneous tissue disorders	2 (<0.1)	2 (<0.1)	1.00 (0.18, 5.66)
Musculoskeletal and connective tissue disorders	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)
Renal and urinary disorders	2 (<0.1)	5 (<0.1)	2.50 (0.56, 11.15)
Reproductive system and breast disorders	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Congenital, familial and genetic disorders	1 (<0.1)	0	



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
General disorders and administration site conditions	5 (<0.1)	4 (<0.1)	0.80 (0.23, 2.75)
Injury, poisoning and procedural complications	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)
Social circumstances	1 (<0.1)	0	
Product issues	1 (<0.1)	0	

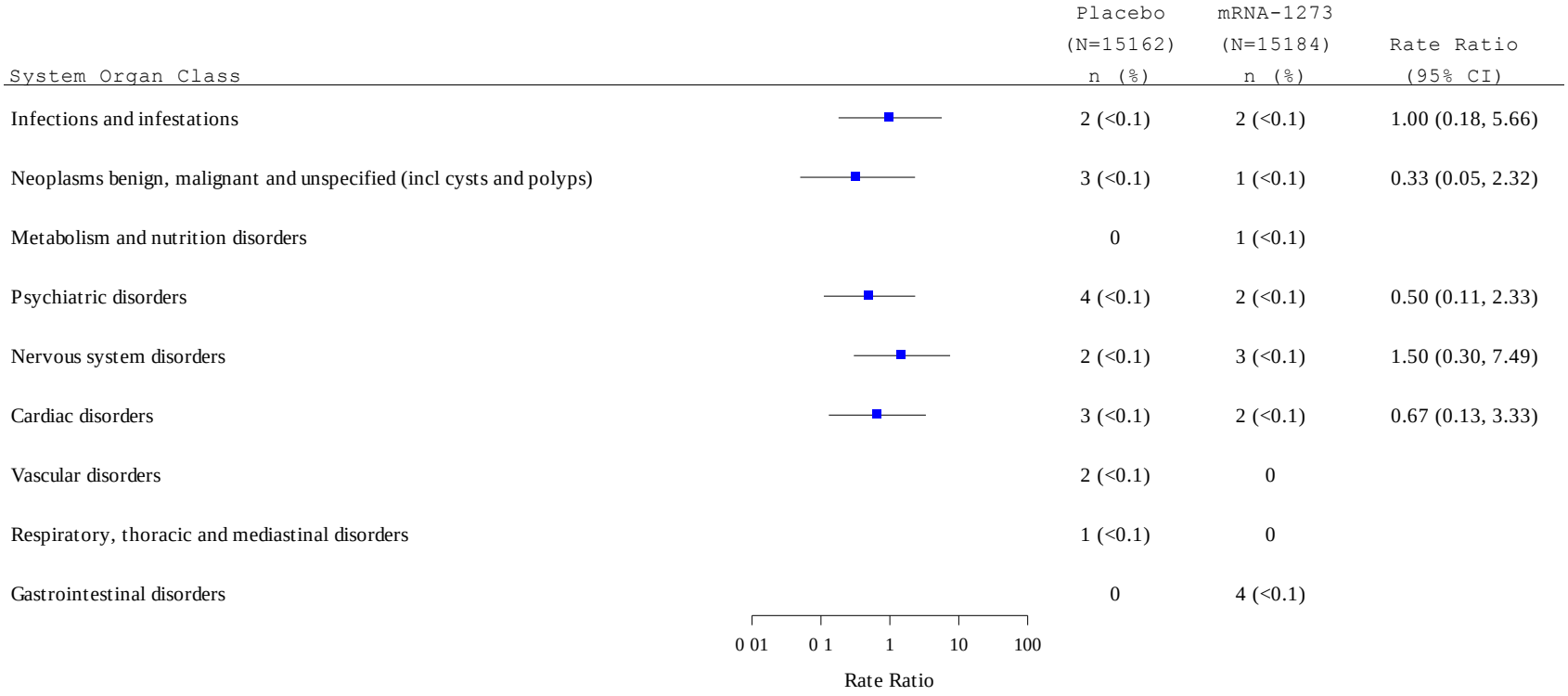


Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.

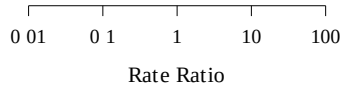
Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0

Source: Figure 14.3.1.13.1.

Figure 3: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class within 7 Days After Any Injection (Safety Set)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Skin and subcutaneous tissue disorders	0	1 (<0.1)	
Musculoskeletal and connective tissue disorders	1 (<0.1)	2 (<0.1)	2.00 (0.26, 15.24)
Renal and urinary disorders	0	2 (<0.1)	
Congenital, familial and genetic disorders	1 (<0.1)	0	
General disorders and administration site conditions	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Injury, poisoning and procedural complications	3 (<0.1)	2 (<0.1)	0.67 (0.13, 3.33)



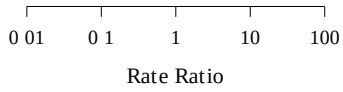
Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.

Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0.

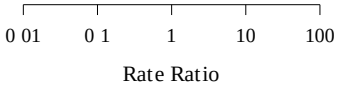
Source: Figure 14.3.1.13.3.

Figure 4: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class Through BLA Data Cut (Safety Set)

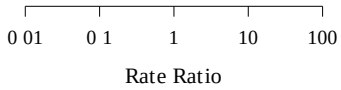
System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Infections and infestations	77 (0.5)	48 (0.3)	0.62 (0.44, 0.89)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)	1.12 (0.65, 1.93)
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)
Immune system disorders	2 (<0.1)	0	
Endocrine disorders	0	1 (<0.1)	
Metabolism and nutrition disorders	15 (<0.1)	17 (0.1)	1.13 (0.57, 2.24)
Psychiatric disorders	13 (<0.1)	13 (<0.1)	1.00 (0.47, 2.12)
Nervous system disorders	27 (0.2)	31 (0.2)	1.15 (0.69, 1.91)
Eye disorders	1 (<0.1)	0	
Cardiac disorders	43 (0.3)	36 (0.2)	0.84 (0.54, 1.30)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Vascular disorders	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)
Respiratory, thoracic and mediastinal disorders	35 (0.2)	25 (0.2)	0.71 (0.43, 1.18)
Gastrointestinal disorders	25 (0.2)	36 (0.2)	1.44 (0.87, 2.38)
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)	1.20 (0.39, 3.70)
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)	1.50 (0.30, 7.49)
Musculoskeletal and connective tissue disorders	28 (0.2)	24 (0.2)	0.86 (0.50, 1.47)
Renal and urinary disorders	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)	0.50 (0.07, 3.81)
Reproductive system and breast disorders	6 (<0.1)	6 (<0.1)	1.00 (0.34, 2.94)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Congenital, familial and genetic disorders	1 (<0.1)	0	
General disorders and administration site conditions	12 (<0.1)	15 (<0.1)	1.25 (0.59, 2.62)
Investigations	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Injury, poisoning and procedural complications	29 (0.2)	27 (0.2)	0.93 (0.55, 1.56)
Social circumstances	1 (<0.1)	0	
Product issues	1 (<0.1)	0	



Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.

Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0.

Source: Figure 14.3.1.13.2.

5.3.2.2 Participants ≥ 18 to < 65 Years of Age

Table 49: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants reporting serious adverse events		14 (0.1)	14 (0.1)
Infections and infestations	Adverse events in any PT	0	1 (<0.1)
	COVID-19	0	1 (<0.1)
	COVID-19 pneumonia	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	2 (<0.1)	3 (<0.1)
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Suicidal ideation	1 (<0.1)	0
	Anxiety	0	1 (<0.1)
	Major depression	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Autonomic nervous system imbalance	1 (<0.1)	0
	Syncope	1 (<0.1)	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	0	2 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
	Sinus tachycardia	0	1 (<0.1)
Vascular disorders	Adverse events in any PT	0	2 (<0.1)
	Hypertensive emergency	0	2 (<0.1)
Respiratory, thoracic and mediastinal disorders	Adverse events in any PT	0	1 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	2 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Inguinal hernia	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	1 (<0.1)	0
	Angioedema	1 (<0.1)	0
Musculoskeletal and connective tissue disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Back pain	1 (<0.1)	0
	Rheumatoid arthritis	1 (<0.1)	0
	Cervical spinal stenosis	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	1 (<0.1)	0
	Nephrolithiasis	1 (<0.1)	0
Congenital, familial and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	3 (<0.1)	1 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Chest pain	1 (<0.1)	0

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Injury, poisoning and procedural complications	Adverse events in any PT	1 (<0.1)	3 (<0.1)
	Tendon rupture	1 (<0.1)	0
	Cartilage injury	0	1 (<0.1)
	Femur fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Ad hoc Table 14.3.1.13.5.2.

Table 50: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants reporting serious adverse events		59 (0.5)	54 (0.5)
Infections and infestations	Adverse events in any PT	7 (<0.1)	8 (<0.1)
	COVID-19	1 (<0.1)	3 (<0.1)
	Clostridium difficile infection	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Pneumonia	1 (<0.1)	1 (<0.1)
	Pneumonia mycoplasmal	1 (<0.1)	0
	Toxic shock syndrome	1 (<0.1)	0
	Appendicitis	0	1 (<0.1)
	COVID-19 pneumonia	0	1 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Diverticulitis	0	1 (<0.1)
	Pyelonephritis acute	0	1 (<0.1)
	Sepsis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	6 (<0.1)	1 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	0
	Pelvic neoplasm	1 (<0.1)	0
	Prostate cancer	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Lung adenocarcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaemia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)
Metabolism and nutrition disorders	Adverse events in any PT	0	3 (<0.1)
	Dehydration	0	1 (<0.1)
	Hypokalaemia	0	1 (<0.1)
	Hyponatraemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	5 (<0.1)	6 (<0.1)
	Alcohol withdrawal syndrome	1 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Drug abuse	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Suicidal ideation	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Depression	0	2 (<0.1)
	Major depression	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	6 (<0.1)	6 (<0.1)
	Autonomic nervous system imbalance	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Seizure	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Syncope	1 (<0.1)	1 (<0.1)
	Transient ischaemic attack	1 (<0.1)	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Cardiac disorders	Adverse events in any PT	5 (<0.1)	8 (<0.1)
	Myocardial infarction	3 (<0.1)	1 (<0.1)
	Cardiac failure congestive	2 (<0.1)	2 (<0.1)
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Atrial flutter	1 (<0.1)	0
	Atrial fibrillation	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
	Pericardial effusion	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	0	5 (<0.1)
	Aortic stenosis	0	1 (<0.1)
	Hypertension	0	1 (<0.1)
	Hypertensive emergency	0	2 (<0.1)
	Hypotension	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	7 (<0.1)	10 (<0.1)
	Acute respiratory failure	2 (<0.1)	2 (<0.1)
	Pulmonary embolism	2 (<0.1)	3 (<0.1)
	Atelectasis	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pleural effusion	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Chronic obstructive pulmonary disease	0	1 (<0.1)
	Hypoxia	0	1 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	11 (<0.1)	4 (<0.1)
	Colitis	2 (<0.1)	1 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Abdominal pain upper	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Inguinal hernia	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Abdominal pain	0	1 (<0.1)
	Gastritis	0	1 (<0.1)
	Nausea	0	1 (<0.1)
	Vomiting	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	2 (<0.1)	0
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	0

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	5 (<0.1)	6 (<0.1)
	Back pain	1 (<0.1)	0
	Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)
	Musculoskeletal chest pain	1 (<0.1)	0
	Osteoarthritis	1 (<0.1)	1 (<0.1)
	Rheumatoid arthritis	1 (<0.1)	0
	Cervical spinal stenosis	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Spinal osteoarthritis	0	1 (<0.1)
	Spinal stenosis	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	3 (<0.1)	0
	Nephrolithiasis	2 (<0.1)	0
	Acute kidney injury	1 (<0.1)	0
Reproductive system and breast disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Benign prostatic hyperplasia	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (<0.1)	3 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Chest pain	1 (<0.1)	1 (<0.1)
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Feeling hot	0	1 (<0.1)
Injury, poisoning, and procedural complications	Adverse events in any PT	4 (<0.1)	8 (<0.1)
	Back injury	1 (<0.1)	0
	Road traffic accident	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Cartilage injury	0	1 (<0.1)
	Fall	0	1 (<0.1)
	Femur fracture	0	1 (<0.1)
	Hip fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Joint injury	0	1 (<0.1)
	Post procedural haemorrhage	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.1.

Table 51: (Table Z) Percentage of Participants Reporting Serious Adverse Events Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants reporting serious adverse events		150 (1.3)	168 (1.5)
Infections and infestations	Adverse events in any PT	30 (0.3)	41 (0.4)
	Pneumonia	4 (<0.1)	8 (<0.1)
	Sepsis	3 (<0.1)	3 (<0.1)
	Cellulitis	2 (<0.1)	0
	Abscess limb	1 (<0.1)	0
	Appendicitis	1 (<0.1)	3 (<0.1)
	Appendicitis perforated	1 (<0.1)	0
	Bronchitis	1 (<0.1)	0
	COVID-19	1 (<0.1)	24 (0.2)
	Clostridium difficile infection	1 (<0.1)	0
	Diabetic foot infection	1 (<0.1)	0
	Diverticulitis	1 (<0.1)	1 (<0.1)
	Gastroenteritis viral	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia mycoplasmal	1 (<0.1)	0
	Post procedural infection	1 (<0.1)	0
	Salpingitis	1 (<0.1)	0
	Septic shock	1 (<0.1)	2 (<0.1)
	Spinal cord abscess	1 (<0.1)	0
	Toxic shock syndrome	1 (<0.1)	0
	Upper respiratory tract infection	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	Viral infection	1 (<0.1)	0
	Wound infection	1 (<0.1)	0
	COVID-19 pneumonia	0	3 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Enterococcal bacteraemia	0	1 (<0.1)
	Meningitis aseptic	0	1 (<0.1)
	Perirectal abscess	0	1 (<0.1)
	Pneumonia bacterial	0	1 (<0.1)
	Pyelonephritis	0	1 (<0.1)
	Pyelonephritis acute	0	1 (<0.1)
	Tooth abscess	0	1 (<0.1)
	Urinary tract infection	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	17 (0.1)	11 (<0.1)
	Benign lung neoplasm	1 (<0.1)	0
	Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Gastric cancer	1 (<0.1)	0
	Gastrointestinal stromal tumour	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
	Invasive lobular breast carcinoma	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Metastatic neoplasm	1 (<0.1)	0
	Non-Hodgkin's lymphoma	1 (<0.1)	0
	Oesophageal carcinoma	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	1 (<0.1)
	Pelvic neoplasm	1 (<0.1)	0
	Prostate cancer	1 (<0.1)	1 (<0.1)
	Renal cell carcinoma	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thymoma malignant	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Adenocarcinoma gastric	0	1 (<0.1)
	Colon cancer stage III	0	1 (<0.1)
	Endometrial cancer	0	2 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Invasive ductal breast carcinoma	0	1 (<0.1)
	Lung adenocarcinoma	0	1 (<0.1)
	Uterine leiomyoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	4 (<0.1)
	Anaemia	1 (<0.1)	1 (<0.1)
	Anaemia macrocytic	0	1 (<0.1)
	Iron deficiency anaemia	0	1 (<0.1)
	Thrombocytopenia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	2 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)
	Cytokine storm	0	1 (<0.1)
Metabolism and nutrition disorders	Adverse events in any PT	8 (<0.1)	11 (<0.1)
	Diabetic ketoacidosis	2 (<0.1)	3 (<0.1)
	Hyponatraemia	2 (<0.1)	1 (<0.1)
	Dehydration	1 (<0.1)	2 (<0.1)
	Diabetic complication	1 (<0.1)	0
	Hypoglycaemia	1 (<0.1)	1 (<0.1)
	Type 2 diabetes mellitus	1 (<0.1)	1 (<0.1)
	Diabetes mellitus	0	1 (<0.1)
	Diabetes mellitus inadequate control	0	1 (<0.1)
	Hypokalaemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Psychiatric disorders	Adverse events in any PT	12 (0.1)	11 (<0.1)
	Depression	3 (<0.1)	2 (<0.1)
	Alcohol withdrawal syndrome	2 (<0.1)	0
	Alcohol abuse	1 (<0.1)	0
	Completed suicide	1 (<0.1)	1 (<0.1)
	Drug abuse	1 (<0.1)	0
	Intentional self-injury	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Substance-induced mood disorder	1 (<0.1)	0
	Substance-induced psychotic disorder	1 (<0.1)	0
	Suicidal ideation	1 (<0.1)	0
	Suicide attempt	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Anxiety disorder	0	1 (<0.1)
	Depression suicidal	0	1 (<0.1)
	Major depression	0	2 (<0.1)
	Mania	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)
	Schizophrenia	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	18 (0.2)	19 (0.2)
	Cerebrovascular accident	3 (<0.1)	2 (<0.1)
	Seizure	3 (<0.1)	1 (<0.1)
	Syncope	3 (<0.1)	5 (<0.1)
	Aphasia	1 (<0.1)	0
	Autonomic nervous system imbalance	1 (<0.1)	0
	Cauda equina syndrome	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Dizziness	1 (<0.1)	0
	Hemiparesis	1 (<0.1)	0
	Multiple sclerosis	1 (<0.1)	1 (<0.1)
	Spinal cord compression	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	2 (<0.1)
	Arachnoid cyst	0	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	2 (<0.1)
	Hydrocephalus	0	1 (<0.1)
	Loss of consciousness	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)
	Retinal tear	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Cardiac disorders	Adverse events in any PT	11 (<0.1)	18 (0.2)
	Myocardial infarction	4 (<0.1)	6 (<0.1)
	Atrial flutter	2 (<0.1)	0
	Cardiac failure congestive	2 (<0.1)	2 (<0.1)
	Coronary artery disease	2 (<0.1)	0
	Acute coronary syndrome	1 (<0.1)	0
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Acute myocardial infarction	1 (<0.1)	2 (<0.1)
	Atrial fibrillation	1 (<0.1)	1 (<0.1)
	Cardiac failure acute	1 (<0.1)	0
	Pericardial effusion	1 (<0.1)	1 (<0.1)
	Pericarditis	1 (<0.1)	2 (<0.1)
	Angina pectoris	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
	Paroxysmal arrhythmia	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	5 (<0.1)	11 (<0.1)
	Deep vein thrombosis	1 (<0.1)	0
	Embolism venous	1 (<0.1)	0
	Haematoma	1 (<0.1)	0
	Polyarteritis nodosa	1 (<0.1)	0
	Venous thrombosis limb	1 (<0.1)	0
	Aortic stenosis	0	1 (<0.1)
	Arterial haemorrhage	0	1 (<0.1)
	Hypertension	0	2 (<0.1)
	Hypertensive emergency	0	2 (<0.1)
	Hypotension	0	2 (<0.1)
	Peripheral artery aneurysm	0	1 (<0.1)
	Peripheral artery occlusion	0	1 (<0.1)
	Thrombophlebitis superficial	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	15 (0.1)	21 (0.2)
	Dyspnoea	5 (<0.1)	0
	Pulmonary embolism	4 (<0.1)	5 (<0.1)
	Acute respiratory failure	3 (<0.1)	5 (<0.1)
	Pleural effusion	2 (<0.1)	1 (<0.1)
	Atelectasis	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Acute respiratory distress syndrome	0	1 (<0.1)
	Chronic obstructive pulmonary disease	0	3 (<0.1)
	Epistaxis	0	1 (<0.1)
	Hypoxia	0	3 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pneumothorax	0	2 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Gastrointestinal disorders	Adverse events in any PT	18 (0.2)	14 (0.1)
	Colitis	2 (<0.1)	4 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Abdominal pain	1 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Crohn's disease	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Gastritis	1 (<0.1)	2 (<0.1)
	Inguinal hernia	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Nausea	1 (<0.1)	2 (<0.1)
	Oesophageal rupture	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Retroperitoneal haemorrhage	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Vomiting	1 (<0.1)	2 (<0.1)
	Abdominal hernia	0	1 (<0.1)
	Abdominal pain lower	0	2 (<0.1)
	Gastric ulcer haemorrhage	0	1 (<0.1)
	Pancreatitis	0	2 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	4 (<0.1)	3 (<0.1)
	Cholecystitis	2 (<0.1)	2 (<0.1)
	Bile duct stone	1 (<0.1)	0
	Cholelithiasis	1 (<0.1)	0
	Biliary dyskinesia	0	1 (<0.1)
Skin and subcutaneous tissue disorders	Adverse events in any PT	3 (<0.1)	0
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	0
	Rash	1 (<0.1)	0
	Rash vesicular	1 (<0.1)	0
Musculoskeletal and connective tissue disorders	Adverse events in any PT	11 (<0.1)	15 (0.1)
	Intervertebral disc protrusion	3 (<0.1)	1 (<0.1)
	Osteoarthritis	3 (<0.1)	2 (<0.1)
	Back pain	1 (<0.1)	0
	Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)
	Rheumatoid arthritis	1 (<0.1)	0
	Spinal osteoarthritis	1 (<0.1)	3 (<0.1)
	Vertebral foraminal stenosis	1 (<0.1)	0
	Arthritis	0	1 (<0.1)
	Cervical spinal stenosis	0	1 (<0.1)
	Flank pain	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Muscular weakness	0	1 (<0.1)
	Rhabdomyolysis	0	1 (<0.1)
	Spinal stenosis	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Renal and urinary disorders	Adverse events in any PT	5 (<0.1)	3 (<0.1)
	Nephrolithiasis	3 (<0.1)	1 (<0.1)
	Acute kidney injury	2 (<0.1)	2 (<0.1)
Pregnancy, puerperium and perinatal conditions	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Abortion spontaneous	1 (<0.1)	1 (<0.1)
	Ectopic pregnancy	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	5 (<0.1)	4 (<0.1)
	Pelvic pain	2 (<0.1)	0
	Benign prostatic hyperplasia	1 (<0.1)	0
	Dysfunctional uterine bleeding	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
	Endometrial hyperplasia	0	1 (<0.1)
	Ovarian cyst	0	2 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	11 (<0.1)	7 (<0.1)
	Death	4 (<0.1)	2 (<0.1)
	Chest pain	2 (<0.1)	2 (<0.1)
	Non-cardiac chest pain	2 (<0.1)	1 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Drug withdrawal syndrome	1 (<0.1)	0
	Feeling hot	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)
Investigations	Adverse events in any PT	2 (<0.1)	0
	Heart rate irregular	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Injury, poisoning, and procedural complications	Adverse events in any PT	13 (0.1)	18 (0.2)
	Back injury	1 (<0.1)	0
	Concussion	1 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Gastrointestinal procedural complication	1 (<0.1)	0
	Head injury	1 (<0.1)	0
	Incision site pain	1 (<0.1)	0
	Joint injury	1 (<0.1)	1 (<0.1)
	Post procedural haemorrhage	1 (<0.1)	1 (<0.1)
	Road traffic accident	1 (<0.1)	0
	Superficial injury of eye	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	1 (<0.1)
	Wound dehiscence	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Ankle fracture	0	1 (<0.1)
	Cartilage injury	0	1 (<0.1)
	Fall	0	3 (<0.1)
	Femur fracture	0	1 (<0.1)
	Gun shot wound	0	1 (<0.1)
	Hip fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Post procedural fever	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
	Skin laceration	0	1 (<0.1)
	Sternal fracture	0	1 (<0.1)
	Tracheal haemorrhage	0	1 (<0.1)
	Traumatic haemothorax	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.3.

5.3.2.3 Participants 65 Years of Age and Older

Table 52: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants reporting serious adverse events		11 (0.3)	6 (0.2)
Infections and infestations	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Appendicitis	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	Urinary tract infection	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	1 (<0.1)	3 (<0.1)
	Prostate cancer	1 (<0.1)	1 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
Metabolism and nutrition disorders	Adverse events in any PT	1 (<0.1)	0
	Dehydration	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	0	1 (<0.1)
	Confusional state	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	1 (<0.1)	0
	Cerebrovascular accident	1 (<0.1)	0
Cardiac disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Atrial fibrillation	1 (<0.1)	0
	Cardiac failure congestive	1 (<0.1)	0
	Cardiac failure	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	2 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Nausea	1 (<0.1)	0
	Vomiting	1 (<0.1)	0
Renal and urinary disorders	Adverse events in any PT	1 (<0.1)	0
	Nephrolithiasis	1 (<0.1)	0
Injury, poisoning and procedural complications	Adverse events in any PT	1 (<0.1)	0
	Femoral neck fracture	1 (<0.1)	0

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Ad hoc Table 14.3.1.13.5.2.

Table 53: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants reporting serious adverse events		39 (1.0)	50 (1.3)
Infections and infestations	Adverse events in any PT	6 (0.2)	11 (0.3)
	Pneumonia	2 (<0.1)	3 (<0.1)
	Appendicitis	1 (<0.1)	2 (<0.1)
	Cellulitis	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	COVID-19	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)
	Urinary tract infection	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	3 (<0.1)	7 (0.2)
	Prostate cancer	2 (<0.1)	3 (<0.1)
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	0
	Blood loss anaemia	1 (<0.1)	0
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Dehydration	2 (<0.1)	1 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	0	1 (<0.1)
	Confusional state	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	4 (0.1)	2 (<0.1)
	Cerebrovascular accident	2 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Embolic stroke	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Syncope	1 (<0.1)	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Cardiac disorders	Adverse events in any PT	9 (0.2)	9 (0.2)
	Atrial fibrillation	3 (<0.1)	2 (<0.1)
	Acute myocardial infarction	2 (<0.1)	1 (<0.1)
	Acute coronary syndrome	1 (<0.1)	0
	Cardiac failure congestive	1 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	1 (<0.1)	0
	Coronary artery disease	1 (<0.1)	2 (<0.1)
	Atrial flutter	0	1 (<0.1)
	Cardiac failure	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	4 (0.1)	3 (<0.1)
	Hypertension	2 (<0.1)	0
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Hypertensive urgency	1 (<0.1)	1 (<0.1)
	Hypotension	1 (<0.1)	0
	Fibromuscular dysplasia	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	2 (<0.1)	5 (0.1)
	Pulmonary embolism	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Acute respiratory failure	0	1 (<0.1)
	Chronic obstructive pulmonary disease	0	2 (<0.1)
	Emphysema	0	1 (<0.1)
	Pleural effusion	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	4 (0.1)	3 (<0.1)
	Nausea	2 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Vomiting	1 (<0.1)	0
	Abdominal pain	0	1 (<0.1)
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	2 (<0.1)	0
	Bile duct stone	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	0	2 (<0.1)
	Angioedema	0	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	4 (0.1)	6 (0.2)
	Spinal stenosis	2 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Osteoarthritis	1 (<0.1)	5 (0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Chronic kidney disease	1 (<0.1)	0
	Nephrolithiasis	1 (<0.1)	0
	Acute kidney injury	0	1 (<0.1)
	Urinary retention	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Reproductive system and breast disorders	Adverse events in any PT	1 (<0.1)	0
	Ovarian cyst	1 (<0.1)	0
General disorders and administration site conditions	Adverse events in any PT	0	2 (<0.1)
	Incarcerated hernia	0	2 (<0.1)
Injury, poisoning, and procedural complications	Adverse events in any PT	6 (0.2)	3 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Fall	1 (<0.1)	0
	Femoral neck fracture	1 (<0.1)	0
	Hip fracture	1 (<0.1)	1 (<0.1)
	Overdose	1 (<0.1)	0
	Road traffic accident	1 (<0.1)	0
	Skin laceration	1 (<0.1)	0
	Subdural haematoma	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Post procedural haematoma	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.1.

Table 54: (Table Z) Percentage of Participants Reporting Serious Adverse Events Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants reporting serious adverse events		118 (3.1)	124 (3.3)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Infections and infestations	Adverse events in any PT	18 (0.5)	36 (1.0)
	Pneumonia	5 (0.1)	3 (<0.1)
	Appendicitis	3 (<0.1)	2 (<0.1)
	Postoperative abscess	2 (<0.1)	0
	Bronchitis	1 (<0.1)	0
	COVID-19	1 (<0.1)	16 (0.4)
	Cellulitis	1 (<0.1)	0
	Giardiasis	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Postoperative wound infection	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	0
	Sepsis	1 (<0.1)	0
	Urinary tract infection	1 (<0.1)	4 (0.1)
	Urosepsis	1 (<0.1)	0
	Viral pharyngitis	1 (<0.1)	0
	Appendicitis perforated	0	1 (<0.1)
	COVID-19 pneumonia	0	5 (0.1)
	Clostridium difficile colitis	0	1 (<0.1)
	Diverticulitis	0	2 (<0.1)
	Localised infection	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Pneumonia klebsiella	0	1 (<0.1)
	Pyelonephritis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	10 (0.3)	13 (0.3)
	Prostate cancer	4 (0.1)	3 (<0.1)
	B-cell small lymphocytic lymphoma	1 (<0.1)	0
	Cancer pain	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
	Liposarcoma	1 (<0.1)	0
	Meningioma	1 (<0.1)	0
	Plasma cell myeloma	1 (<0.1)	0
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Endometrial cancer	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	2 (<0.1)
	Leiomyosarcoma metastatic	0	1 (<0.1)
	Non-small cell lung cancer	0	1 (<0.1)
	Pancreatic carcinoma stage IV	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
	Thyroid cancer	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Blood and lymphatic system disorders	Adverse events in any PT	2 (<0.1)	3 (<0.1)
	Anaemia	1 (<0.1)	1 (<0.1)
	Blood loss anaemia	1 (<0.1)	1 (<0.1)
	Thrombocytopenia	1 (<0.1)	0
	Thrombocytosis	0	1 (<0.1)
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	9 (0.2)	4 (0.1)
	Dehydration	3 (<0.1)	2 (<0.1)
	Diabetic ketoacidosis	1 (<0.1)	0
	Failure to thrive	1 (<0.1)	0
	Gout	1 (<0.1)	1 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
	Hypoglycaemia	1 (<0.1)	0
	Hypokalaemia	1 (<0.1)	0
	Hyponatraemia	1 (<0.1)	0
	Obesity	1 (<0.1)	0
	Type 2 diabetes mellitus	1 (<0.1)	0
	Hypomagnesaemia	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Mental status changes	1 (<0.1)	0
	Alcohol withdrawal syndrome	0	1 (<0.1)
	Confusional state	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	13 (0.3)	8 (0.2)
	Cerebrovascular accident	3 (<0.1)	2 (<0.1)
	Embolic stroke	2 (<0.1)	0
	Subarachnoid haemorrhage	2 (<0.1)	0
	Syncope	2 (<0.1)	2 (<0.1)
	Carotid artery stenosis	1 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Facial paralysis	1 (<0.1)	0
	Lumbar radiculopathy	1 (<0.1)	0
	Optic neuritis	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	0
	Amyotrophic lateral sclerosis	0	1 (<0.1)
	Dizziness	0	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Nerve compression	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Cardiac disorders	Adverse events in any PT	25 (0.7)	25 (0.7)
	Atrial fibrillation	5 (0.1)	9 (0.2)
	Myocardial infarction	3 (<0.1)	3 (<0.1)
	Acute coronary syndrome	2 (<0.1)	0
	Acute myocardial infarction	2 (<0.1)	4 (0.1)
	Cardiac failure congestive	2 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	2 (<0.1)	0
	Angina unstable	1 (<0.1)	0
	Bradycardia	1 (<0.1)	0
	Cardiac arrest	1 (<0.1)	0
	Cardiac failure	1 (<0.1)	2 (<0.1)
	Coronary artery disease	1 (<0.1)	3 (<0.1)
	Coronary artery occlusion	1 (<0.1)	0
	Pericarditis	1 (<0.1)	0
	Stress cardiomyopathy	1 (<0.1)	0
	Supraventricular tachycardia	1 (<0.1)	0
	Ventricular extrasystoles	1 (<0.1)	0
	Acute left ventricular failure	0	1 (<0.1)
	Arrhythmia	0	1 (<0.1)
	Atrial flutter	0	2 (<0.1)
	Atrioventricular block complete	0	1 (<0.1)
	Atrioventricular block second degree	0	1 (<0.1)
	Cardiac failure acute	0	1 (<0.1)
Vascular disorders	Adverse events in any PT	10 (0.3)	4 (0.1)
	Deep vein thrombosis	3 (<0.1)	1 (<0.1)
	Hypertension	2 (<0.1)	0
	Hypertensive urgency	2 (<0.1)	1 (<0.1)
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Arteriosclerosis	1 (<0.1)	0
	Axillary vein thrombosis	1 (<0.1)	0
	Haematoma	1 (<0.1)	0
	Hypotension	1 (<0.1)	0
	Fibromuscular dysplasia	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	10 (0.3)	14 (0.4)
	Acute respiratory failure	4 (0.1)	5 (0.1)
	Pulmonary embolism	2 (<0.1)	2 (<0.1)
	Chronic obstructive pulmonary disease	1 (<0.1)	5 (0.1)
	Emphysema	1 (<0.1)	1 (<0.1)
	Pneumothorax	1 (<0.1)	0
	Pulmonary mass	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	1 (<0.1)
	Asthma	0	1 (<0.1)
	Organising pneumonia	0	1 (<0.1)
	Pleural effusion	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Gastrointestinal disorders	Adverse events in any PT	18 (0.5)	11 (0.3)
	Gastrointestinal haemorrhage	3 (<0.1)	2 (<0.1)
	Duodenal ulcer perforation	2 (<0.1)	0
	Nausea	2 (<0.1)	1 (<0.1)
	Small intestinal obstruction	2 (<0.1)	2 (<0.1)
	Abdominal pain	1 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Colitis	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	1 (<0.1)
	Diverticular perforation	1 (<0.1)	0
	Gastrooesophageal reflux disease	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Intra-abdominal fluid collection	1 (<0.1)	0
	Oesophageal spasm	1 (<0.1)	0
	Pancreatitis	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Vomiting	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
	Hiatus hernia	0	1 (<0.1)
	Tooth socket haemorrhage	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Bile duct stone	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	1 (<0.1)
	Cholecystitis acute	0	1 (<0.1)
Skin and subcutaneous tissue disorders	Adverse events in any PT	0	2 (<0.1)
	Angioedema	0	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	13 (0.3)	13 (0.3)
	Osteoarthritis	5 (0.1)	10 (0.3)
	Spinal stenosis	2 (<0.1)	0
	Back pain	1 (<0.1)	0
	Flank pain	1 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Muscular weakness	1 (<0.1)	0
	Neck pain	1 (<0.1)	0
	Spondylolisthesis	1 (<0.1)	0
	Intervertebral disc protrusion	0	1 (<0.1)
	Osteonecrosis	0	1 (<0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	5 (0.1)	8 (0.2)
	Acute kidney injury	3 (<0.1)	4 (0.1)
	Nephrolithiasis	2 (<0.1)	0
	Chronic kidney disease	1 (<0.1)	2 (<0.1)
	Renal impairment	0	1 (<0.1)
	Urinary retention	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Reproductive system and breast disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Ovarian cyst	1 (<0.1)	0
	Benign prostatic hyperplasia	0	1 (<0.1)
	Pelvic prolapse	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (0.1)	5 (0.1)
	Asthenia	1 (<0.1)	0
	Generalised oedema	1 (<0.1)	0
	Multiple organ dysfunction syndrome	1 (<0.1)	0
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Oedema peripheral	1 (<0.1)	0
	Incarcerated hernia	0	2 (<0.1)
	Pyrexia	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)
Investigations	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Hepatic enzyme increased	1 (<0.1)	0
	Transaminases increased	0	1 (<0.1)
Injury, poisoning, and procedural complications	Adverse events in any PT	14 (0.4)	11 (0.3)
	Hip fracture	3 (<0.1)	2 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Fall	2 (<0.1)	2 (<0.1)
	Subdural haematoma	2 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Femoral neck fracture	1 (<0.1)	0
	Femur fracture	1 (<0.1)	1 (<0.1)
	Humerus fracture	1 (<0.1)	0
	Incarcerated incisional hernia	1 (<0.1)	0
	Overdose	1 (<0.1)	0
	Procedural haemorrhage	1 (<0.1)	0
	Rib fracture	1 (<0.1)	2 (<0.1)
	Road traffic accident	1 (<0.1)	1 (<0.1)
	Skin laceration	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Pelvic fracture	0	1 (<0.1)
	Post procedural haematoma	0	1 (<0.1)
	Post-traumatic pain	0	1 (<0.1)
	Thoracic vertebral fracture	0	1 (<0.1)
	Traumatic haemothorax	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.3.

5.3.2.4 Serious Adverse Events Considered Related by Investigator (Safety Set)

Table 55 (Table AA) Serious Adverse Events Considered Related by Investigator (Safety Set)

Product	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	SAE Preferred Term	Risk Factors	Resolution	Related per Moderna
mRNA-1273	US3212326	46/F	2	1	Autonomic nervous system imbalance	Hypothyroidism, left thyroidectomy, benign left thyroid nodule	Resolved with sequelae	Not related
mRNA-1273	US3322329	51/F	2	3	Swelling face	Dermal filler injections to face 13 days prior to Dose 2	Resolved	Related
mRNA-1273	US3522109	59/F	2	68	Pericardial effusion	Flublok (RIV4) vaccination, history of sinus congestion, history of dilatation of the ascending aorta	Resolved	Related
				68	Pericarditis		Resolved	Related
				69	Pleural effusion		Resolved	Related
mRNA-1273	US3542108	46/F	2	1	Swelling face	Bilateral hyaluronic acid cheek injections 5 months before enrollment	Resolved	Related
mRNA-1273	US3552053	65/F	2	1	Nausea	History of headache-induced nausea/vomiting leading to hospitalizations, concomitant headache and fever with nausea/vomiting	Resolved	Related
				1	Vomiting		Resolved	Related
mRNA-1273	US3552191	66/F	2	8	Basedow's disease	History of rosacea and Meniere's disease	Resolved with sequelae	Not related
mRNA-1273	US3652038	34/F	1	67	Cerebrovascular accident	COVID-19 infection 1 month prior; prominent patent foramen ovale	Resolved	Not related
mRNA-1273	US3742077	29/F	2	2	Angioedema	Angioedema following flu vaccine; treatment with Restylane injection on lips about 1.5 years before Dose 2	Resolved	Related
mRNA-1273	US3742169	57/M	1	1	Rheumatoid arthritis	Hypothyroidism, outer thigh pain reported at enrollment/prior to dosing	Resolving	Related

Product	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	SAE Preferred Term	Risk Factors	Resolution	Related per Moderna
mRNA-1273	US3812085	31/M	2	9	Alopecia areata[a]	Herpes simplex virus II, previous history of facial hair loss	Not resolved	Not related
mRNA-1273	US3812291	36/F	2	72	Multiple sclerosis	None known	Not resolved	Not related
mRNA-1273	US3822043	75/F	2	30	B-cell small lymphocytic lymphoma	History of metastatic lung cancer and breast cancer	Resolved with sequelae	Not related
Placebo	US3432023	83/M	1	16	Polymyalgia rheumatica	Monoclonal gammopathy of undetermined significance (MGUS), hypothyroidism	Resolving	Not related
Placebo	US3552232	70/M	1	29	Acute myocardial infarction	History of myocardial infarction, coronary artery disease with percutaneous intervention/stent placement, hypertension, hyperlipidemia, diabetes mellitus type 2, chronic kidney disease, obesity, advanced age	Resolved	Not related
				29	Hypomagnesaemia		Resolved	Not related
				29	Acute kidney injury		Resolved	Not related
				29	Atrial fibrillation		Resolved with sequelae	Not related
				29	Organising pneumonia		Resolved	Not related
				31	Respiratory failure		Resolved	Not related
Placebo	US3602030	41/F	2	7	Swelling face	Recent root canal procedure, history of multiple sinus surgeries, and concomitant Nexplanon implant	Resolved	Not related
				7	Paraesthesia		Resolved	Not related
				7	Immunisation anxiety related reaction		Resolved	Not related
				26	Feeling hot		Resolved	Not related
				26	Paraesthesia		Resolved	Not related
Placebo	US3602051	52/M	2	16	Procedural haemorrhage	Cardiopulmonary bypass, intravenous heparin intraoperatively	Resolved	Not related

Abbreviations: COVID-19=coronavirus disease 2019; F=female; IP=investigational product; M=male; SAE=serious adverse event.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Unless otherwise noted, the table presents only data that were available as of the database lock date (04 May 2021).

[a] This event did not meet SAE criteria based on further information and review after database lock.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Listing 16.2.7.10 and Appendix 16.3.1.

5.3.3 Unsolicited Adverse Events Leading to Study Withdrawal

5.3.3.1 Participants ≥ 18 to < 65 Years of Age

Table 56: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants with adverse events leading to study withdrawal		1 (<0.1)	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	0
Cardiac disorders	Adverse events in any PT	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Ad hoc Table 14.3.1.16.2.4.

Table 57: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants with adverse events leading to study withdrawal		7 (<0.1)	3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	1 (<0.1)	0
	Colorectal cancer	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	3 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	0
	Substance abuse	1 (<0.1)	0
Cardiac disorders	Adverse events in any PT	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	1 (<0.1)	0
	Pulmonary embolism	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Urticaria	1 (<0.1)	0
	Dermatitis allergic	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	1 (<0.1)	0
	Induration	1 (<0.1)	0
Investigations	Adverse events in any PT	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0
Injury, poisoning, and procedural complications	Adverse events in any PT	1 (<0.1)	0
	Hip fracture	1 (<0.1)	0

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.1.

Table 58: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants with adverse events leading to study withdrawal		15 (0.1)	15 (0.1)
Infections and infestations	Adverse events in any PT	0	3 (<0.1)
	COVID-19	0	3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	3 (<0.1)	0
	Colorectal cancer	1 (<0.1)	0
	Gastric cancer	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	1 (<0.1)	0
	Diabetic complication	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	3 (<0.1)	2 (<0.1)
	Completed suicide	1 (<0.1)	1 (<0.1)
	Schizoaffective disorder	1 (<0.1)	0
	Substance abuse	1 (<0.1)	0
	Depression suicidal	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	0	1 (<0.1)
	Seizure	0	1 (<0.1)
Ear and labyrinth disorders	Adverse events in any PT	0	1 (<0.1)
	Vertigo	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	1 (<0.1)	3 (<0.1)
	Coronary artery disease	1 (<0.1)	0
	Cardio-respiratory arrest	0	1 (<0.1)
	Myocardial infarction	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	0	1 (<0.1)
	Hypertension	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	1 (<0.1)	0
	Pulmonary embolism	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Urticaria	1 (<0.1)	0
	Dermatitis allergic	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	5 (<0.1)	2 (<0.1)
	Death	4 (<0.1)	2 (<0.1)
	Induration	1 (<0.1)	0
Investigations	Adverse events in any PT	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0
Injury, poisoning, and procedural complications	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Head injury	1 (<0.1)	0
	Hip fracture	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.3.

5.3.3.2 Participants 65 Years of Age and Older

Table 59: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
There are no observations for this section.			

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Ad hoc Table 14.3.1.16.2.4.

Table 60: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants with adverse events leading to study withdrawal		2 (<0.1)	3 (<0.1)
Cardiac disorders	Adverse events in any PT	1 (<0.1)	0
	Cardio-respiratory arrest	1 (<0.1)	0
Gastrointestinal disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Pancreatitis acute	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	0	1 (<0.1)
	Incarcerated hernia	0	1 (<0.1)

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.1.

Table 61: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants with adverse events leading to study withdrawal		11 (0.3)	8 (0.2)
Infections and infestations	Adverse events in any PT	1 (<0.1)	0
	COVID-19	1 (<0.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	0	1 (<0.1)
	Hepatic cancer	0	1 (<0.1)
	Pancreatic carcinoma stage IV	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	0	1 (<0.1)
	Amyotrophic lateral sclerosis	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	6 (0.2)	2 (<0.1)
	Cardio-respiratory arrest	2 (<0.1)	0
	Myocardial infarction	2 (<0.1)	2 (<0.1)
	Cardiac arrest	1 (<0.1)	0
	Cardiac failure congestive	1 (<0.1)	0
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	3 (<0.1)	0
	Acute respiratory failure	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pulmonary mass	1 (<0.1)	0
Gastrointestinal disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Gastrointestinal haemorrhage	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Multiple organ dysfunction syndrome	1 (<0.1)	0
	Incarcerated hernia	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.3.

5.4 Deaths

Table 62: (Table CC) Deaths Through 04 May 2021 – Part A and Part B (Safety Set)

Product (Vaccine or Placebo)	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	Cause of Death	Risk Factors Relevant to Cause of Death
mRNA-1273	US3292023	80/M	2	145	Cardiac failure congestive	Brittle diabetes mellitus, coronary artery disease with multiple stents and recent STEMI requiring additional intervention and stents x2, recent fall resulting in femur fracture and complicated hospital admission x1 month
mRNA-1273	US3422244	65/M	2	89	Cardiac arrest	Unknown – no significant medical history or concomitant medications reported; autopsy and toxicology reports requested, but not provided
mRNA-1273	US3472001	70/M	2	58	Myocardial infarction	Hypertension, hyperlipidemia, obesity, Wolff-Parkinson-White syndrome, atrial fibrillation
mRNA-1273	US3512042	78/M	1	21	Cardio-respiratory arrest	Hypertension, hypercholesterolemia, paroxysmal atrial fibrillation, illness for 2 days prior to death reported as nausea with episodes of vomiting; no other symptoms
mRNA-1273	US3622169	56/M	2	107	Hepatocellular carcinoma	Severe obesity (BMI 49.6), diabetes mellitus, advanced hepatocellular carcinoma with metastases to the lungs on diagnosis
mRNA-1273	US3702010	74/M	1	175	COVID-19	COVID-19 pneumonia; comorbidities of HIV, hypertension, and hepatitis C cirrhosis
mRNA-1273	US3752173	77/M	2	45	Myocardial infarction	Coronary artery disease, hypercholesterolemia, prior myocardial infarction, hypertension, and hyperlipidemia
mRNA-1273	US3822443	75/F	2	108	Pulmonary mass[a]	Chronic obstructive pulmonary disease requiring oxygen, likely primary lung malignancy on imaging one month prior

Product (Vaccine or Placebo)	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	Cause of Death	Risk Factors Relevant to Cause of Death
mRNA-1273	US3862141	72/M	2	155	Cardio-respiratory arrest	Congestive heart failure with EF of 20%, atrial fibrillation, automatic implantable cardioverter defibrillator, diabetes mellitus type 2, hypertension, and hyperlipidemia
mRNA-1273	US3872318	62/M	1	21	Completed suicide	Depression and prior suicidal ideation
mRNA-1273	US3872496	61/M	2	70	Death	Comorbidities of chronic obstructive pulmonary disease, hypertension, and diabetes mellitus type 2
mRNA-1273	US3912024	72/M	2	60	Gastrointestinal haemorrhage, multiple organ dysfunction syndrome, acute respiratory failure	Hepatic cirrhosis, acute kidney injury due to obstructing nephrolithiasis, post-operative heparin administration, thrombocytopenia, Crohn's disease, and perforated duodenal ulcer
mRNA-1273	US3932197	37/F	2	138	Death (updated to "toxicity due to various agents"[b])	Fentanyl and alcohol intoxication
mRNA-1273	US3932246	37/F	2	54	Head injury (updated to "toxicity to various agents"[b])	Fentanyl toxicity, post-traumatic stress disorder, depression, anxiety, drug use disorder, and history of suicidal ideation
mRNA-1273	US3962094	56/F	1	37	Head injury	Found dead after apparent fall with head trauma noted, ongoing chronic pain issues with concomitant gabapentin and hydrocodone use, as well as hypertension with concomitant lisinopril and hydrochlorothiazide use
mRNA-1273	US3972010	59/M	2	110	Death	Death resulted from "self-induced activity;" drug overdose suspected[b]
mRNA-1273	US3972045	62/M	2	71	Coronary artery disease, diabetic complication	Diabetes mellitus type 2, hypertension, hypercholesterolemia, and diabetic ulcer left foot

Product (Vaccine or Placebo)	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	Cause of Death	Risk Factors Relevant to Cause of Death
mRNA-1273	US3202375	56/F	2	182	Sudden death (updated to "toxicity to various agents")[b][c]	No significant medical history/concomitant medications reported; overdose of methamphetamine and diphenhydramine
mRNA-1273	US3222017	72/F	2	155	Cardiac arrest[c]	Coronary artery disease with history of cardiac stent placement x2 and endarterectomy
mRNA-1273	US3302465	69/M	2	95	Myocardial infarction[c]	Diabetes mellitus type 2, hypertension, and chronic obstructive pulmonary disease
mRNA-1273	US3312006	62/M	2	184	Acute myocardial infarction[c]	Autopsy revealed hypertensive and atherosclerotic heart disease
mRNA-1273	US3412151	71/M	2	210	Cerebrovascular accident[c]	Intra/post-operative stroke following aortic valve replacement
mRNA-1273	US3572251	41/M	2	180	Head injury[c]	Alcohol intoxication leading to fall down stairs
mRNA-1273	US3702046	49/M	2	130	Pulmonary embolism[c]	Morbid obesity, hypertension, physical and chemical restraints for preceding 3 days due to psychotic episode, anticoagulant therapy initiated for pulmonary embolism
				138	Pulseless electrical activity, gastrointestinal haemorrhage[c]	
Placebo-mRNA-1273	US3222524	79/M	2	27[d]	Cardiac failure congestive, gastrointestinal haemorrhage, anticoagulation drug level above therapeutic[c]	Stage 3 chronic kidney disease, prior congestive heart failure, chronic atrial fibrillation requiring anticoagulation (warfarin)
Placebo-mRNA-1273	US3242089	30/F	2	8[d]	Accidental overdose[c]	Overdose of cocaine, fentanyl, and xylazine; history of bipolar disorder and anxiety
Placebo-mRNA-1273	US3442074	61/F	2	40[d]	Cerebrovascular accident[c]	Uncontrolled diabetes mellitus type 2 (HbA1C 8.7%), hypertension, and current smoker

Product (Vaccine or Placebo)	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	Cause of Death	Risk Factors Relevant to Cause of Death
Placebo	US3032204	54/M	2	64	COVID-19	Diabetic with rapid progression of COVID-19 infection
Placebo	US3082269	75/M	1	13	Gastric perforation	Hiatal hernia and gastroesophageal reflux disease
Placebo	US3192569	76/M	2	145	Pancreatic carcinoma stage IV	Advanced malignancy with metastases
Placebo	US3232048	73/M	2	86	Amyotrophic lateral sclerosis	Pre-existing history of amyotrophic lateral sclerosis
Placebo	US3272070	74/M	2	29	Myocardial infarction	Diabetes mellitus type 2, hypertension, hypercholesterolemia, chronic obstructive pulmonary disease
Placebo	US3302395	67/M	2	103	Myocardial infarction	Age, concomitant use of trazadone
Placebo	US3322199	64/M	2	47	Myocardial infarction	Obesity, hypercholesterolemia, hyperlipidemia, hypertension, supraventricular tachycardia
Placebo	US3342256	43/M	1	7	Cardio-respiratory arrest	Autopsy revealed extensive coronary artery disease, cardiomegaly, left ventricular hypertrophy, obesity
Placebo	US3372228	55/M	2	120	Death	Diabetes mellitus type 2, hypertension, obesity, recent surgical procedure (5 days previously)
Placebo	US3432295	83/M	1	38	Systemic inflammatory response syndrome	Progression of chronic lymphocytic leukemia
Placebo	US3572086	63/M	2	143	COVID-19	COVID-19 pneumonia; comorbidities of hypertension, hyperlipidemia, diabetes mellitus type 2, and history of cerebrovascular accident x2 with residual right hemiparesis
Placebo	US3672203	25/M	2	87	Completed suicide	Anxiety disorder
Placebo	US3812060	62/M	2	86	Myocardial infarction	Hypercholesterolemia, concomitant use of bupropion hydrochloride and duloxetine hydrochloride

Product (Vaccine or Placebo)	Participant Number	Age/Sex	Number of Doses	Relative Day Since Last Dose	Cause of Death	Risk Factors Relevant to Cause of Death
Placebo	US3832237	50/M	2	64	Death	Alcohol abuse and suicidal tendencies
Placebo	US3882011	59/M	2	97	Seizure	Methamphetamine dependence, methamphetamine and methylenedioxymethamphetamine positive on toxicology report, acute myocardial infarction, hypertensive heart disease, diabetes mellitus, and obesity
Placebo	US3952094	57/M	2	109	COVID-19	COVID-19 pneumonia with comorbidities of hypertension and diabetes mellitus
Placebo	US3932147	84/F	1	128	Ventricular arrhythmia[c]	Concurrent COVID-19 pneumonia, congestive heart failure, chronic kidney disease, atrial fibrillation, and chronic obstructive pulmonary disease

Abbreviations: BMI=body mass index; COVID-19=coronavirus disease 2019; EF=ejection fraction; F=female; HbA1C=glycated hemoglobin; HIV=human immunodeficiency virus; IP=investigational product; M=male; NA=not applicable; STEMI=ST-segment elevation myocardial infarction.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. All deaths through the database lock of 04 May 2021 are presented. Unless otherwise noted, the table presents only data that were available as of the database lock date (04 May 2021).

[a] The event started during Part A, but the fatal outcome occurred during Part B.
[b] Updated with information received after the database lock.
[c] The event occurred during Part B.
[d] Days since last dose for placebo-mRNA-1273 participants is the days since last dose of mRNA-1273.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Listing 16.2.7.14, Listing 16.2.12, and Appendix 16.3.1; mRNA-1273-P301 Clinical Study Report Addendum 1 (Part B) Listing 16.2.7.10, Listing 16.2.7.9.3, and Appendix 16.3.1.

5.5 Pregnancies

Table 63: (Table CC) Pregnancies Reported in Part A, Based on Original Randomization (Safety Set)

	mRNA-1273 N=15184 n (%)	Placebo N=15162 n (%)	Total N=30346 n (%)
Total number of pregnancies	16 (0.1)	11 (<0.1)	27 (<0.1)
Timing of pregnancy			
Completed 1 dose	4 (<0.1)	7 (<0.1)	11 (<0.1)
Completed 2 doses	12 (<0.1)	4 (<0.1)	16 (<0.1)
Timing of last dose relative to pregnancy			
Within 30 days of pregnancy	6 (<0.1)	8 (<0.1)	14 (<0.1)
>30 days after pregnancy	10 (<0.1)	3 (<0.1)	14 (<0.1)
Known outcomes	3 (<0.1)	5 (<0.1)	8 (<0.1)
Spontaneous abortion	2 (<0.1)[a]	3 (<0.1)	5 (<0.1)[a]
Elective abortion	1 (<0.1)	1 (<0.1)	2 (<0.1)[b]
Delivered full term	0	1 (<0.1)[c, d]	1 (<0.1)[c, d]

[a] The outcome of spontaneous abortion/miscarriage for 1 participant occurred after the Participant Decision Visit and is therefore reported as a serious adverse event in the Part B addendum to the Part A Clinical Study Report. See Table 64.
[b] There were no reported pregnancy complications in either group.
[c] Reported in Clinical Study Report as "live born;" baby was born at 37 weeks with congenital anomalies of bilateral talipes equinovarus and hydronephrosis.
[d] The mother of the baby with talipes equinovarus and hydronephrosis had polyhydramnios and gestational diabetes.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 7-28, Table 14.1.2.2, and Appendix 16.3.1.

Table 64: (Table CC) Pregnancies Reported in Cross-Over Participants (Participants Originally Randomized to Placebo and Received at Least 1 Dose of mRNA-1273 After Unblinding)

	Placebo-mRNA-1273 (N=12648) n (%)
Total number of pregnancies	19 (0.2)
Timing of pregnancy	
Completed 1 dose	11 (<0.1)
Completed 2 doses	7 (<0.1)
Unknown	1 (<0.1)
Timing of last dose relative to pregnancy	
Within 30 days of pregnancy	14 (0.1)
>30 days after pregnancy	4 (<0.1)
Unknown	1 (<0.1)

	Placebo-mRNA-1273 (N=12648) n (%)
Known outcomes	
Spontaneous abortion	3 (<0.1)
Elective abortion	1[a] (<0.1)

[a] There were no reported pregnancy complications.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Appendix 16.3.1; mRNA-1273-P301 Clinical Study Report Addendum 1 (Part B) Table 7-4, Table 14.1.1.1.5.5.

5.6 SMQ Analysis

5.6.1 Embolic and Thrombotic Events

Table 65: Participant Incidence of Embolic and Thrombotic Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting embolic and thrombotic events	47 (0.3)	43 (0.3)
Number of embolic and thrombotic events	54	45
Acute myocardial infarction	4 (<0.1)	6 (<0.1)
Arterial occlusive disease	1 (<0.1)	0
Axillary vein thrombosis	1 (<0.1)	0
Blindness transient	1 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Coronary artery occlusion	2 (<0.1)	0
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Embolic stroke	2 (<0.1)	0
Embolism venous	1 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Myocardial infarction	7 (<0.1)	9 (<0.1)
Peripheral arterial occlusive disease	1 (<0.1)	0
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)
Pulmonary embolism	6 (<0.1)	7 (<0.1)
Pulmonary infarction	0	1 (<0.1)
Retinal infarction	0	1 (<0.1)
Stress cardiomyopathy	1 (<0.1)	0
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Venous thrombosis limb	1 (<0.1)	0
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Embolic and thrombotic events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.12.4.

Table 66: Participant Incidence of Embolic and Thrombotic Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting embolic and thrombotic events	47 (0.3)	43 (0.3)
Number of embolic and thrombotic events	54	45
Acute myocardial infarction	4 (<0.1)	6 (<0.1)
Arterial occlusive disease	1 (<0.1)	0
Axillary vein thrombosis	1 (<0.1)	0
Blindness transient	1 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Coronary artery occlusion	2 (<0.1)	0
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Embolic stroke	2 (<0.1)	0
Embolism venous	1 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Myocardial infarction	7 (<0.1)	9 (<0.1)
Peripheral arterial occlusive disease	1 (<0.1)	0
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)
Pulmonary embolism	6 (<0.1)	7 (<0.1)
Pulmonary infarction	0	1 (<0.1)
Retinal infarction	0	1 (<0.1)
Stress cardiomyopathy	1 (<0.1)	0
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Venous thrombosis limb	1 (<0.1)	0
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Embolic and thrombotic events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.12.

5.6.2 Hearing and Vestibular Disorder Events

Table 67: Participant Incidence of Hearing and Vestibular Disorder Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hearing and vestibular disorder events	192 (1.3)	171 (1.1)
Number of hearing and vestibular disorder events	203	186
Balance disorder	1 (<0.1)	2 (<0.1)
Deafness neurosensory	2 (<0.1)	0
Deafness unilateral	3 (<0.1)	2 (<0.1)
Diplacusis	0	1 (<0.1)
Dizziness	97 (0.6)	88 (0.6)
Eustachian tube dysfunction	2 (<0.1)	4 (<0.1)
Facial paralysis	8 (<0.1)	3 (<0.1)
Hyperacusis	0	1 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)
Labyrinthitis	1 (<0.1)	1 (<0.1)
Meniere's disease	6 (<0.1)	2 (<0.1)
Middle ear effusion	1 (<0.1)	3 (<0.1)
Motion sickness	2 (<0.1)	0
Tinnitus	20 (0.1)	22 (0.1)
Tympanic membrane disorder	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	9 (<0.1)
Vertigo	46 (0.3)	34 (0.2)
Vertigo positional	8 (<0.1)	4 (<0.1)
Vestibular migraine	1 (<0.1)	0
Vestibular neuronitis	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hearing and vestibular disorder events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.13.4.

Table 68: Participant Incidence of Hearing and Vestibular Disorder Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hearing and vestibular disorder events	88 (0.6)	81 (0.5)
Number of hearing and vestibular disorder events	92	88
Deafness neurosensory	2 (<0.1)	0
Deafness unilateral	3 (<0.1)	2 (<0.1)
Diplacusis	0	1 (<0.1)
Eustachian tube dysfunction	2 (<0.1)	4 (<0.1)
Hyperacusis	0	1 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)
Meniere's disease	6 (<0.1)	2 (<0.1)
Middle ear effusion	1 (<0.1)	3 (<0.1)
Tinnitus	20 (0.1)	22 (0.1)
Tympanic membrane disorder	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	9 (<0.1)
Vertigo	46 (0.3)	34 (0.2)
Vertigo positional	8 (<0.1)	4 (<0.1)
Vestibular migraine	1 (<0.1)	0
Vestibular neuronitis	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hearing and vestibular disorder events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.13.

5.6.3 Angioedema Events

Table 69: Participant Incidence of Angioedema Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting angioedema events	142 (0.9)	133 (0.9)
Number of angioedema events	155	145
Angioedema	3 (<0.1)	3 (<0.1)
Breast swelling	1 (<0.1)	0
Choking sensation	1 (<0.1)	0
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eye swelling	2 (<0.1)	5 (<0.1)
Generalised oedema	1 (<0.1)	0
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Oedema	0	1 (<0.1)
Oedema peripheral	14 (<0.1)	17 (0.1)
Orbital oedema	0	1 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Peripheral swelling	19 (0.1)	14 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Swelling	1 (<0.1)	2 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Throat tightness	0	2 (<0.1)
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Wheezing	5 (<0.1)	11 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Angioedema events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.4.4.

Table 70: Participant Incidence of Angioedema Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting angioedema events	82 (0.5)	71 (0.5)
Number of angioedema events	91	79
Angioedema	3 (<0.1)	3 (<0.1)
Eye swelling	2 (<0.1)	5 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Angioedema events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.4.

5.6.4 Arthritis Events

Table 71: Participant Incidence of Arthritis Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting arthritis events	648 (4.3)	635 (4.2)
Number of arthritis events	724	706
Arthralgia	443 (2.9)	436 (2.9)
Arthritis	14 (<0.1)	12 (<0.1)
Chondrocalcinosis pyrophosphate	1 (<0.1)	0
Facet joint syndrome	2 (<0.1)	0
Gout	13 (<0.1)	17 (0.1)
Injection site joint pain	5 (<0.1)	2 (<0.1)
Joint abscess	1 (<0.1)	0
Joint effusion	0	1 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)
Joint range of motion decreased	5 (<0.1)	1 (<0.1)
Joint stiffness	2 (<0.1)	3 (<0.1)
Joint swelling	10 (<0.1)	11 (<0.1)
Musculoskeletal stiffness	15 (<0.1)	16 (0.1)
Neck pain	62 (0.4)	54 (0.4)
Osteoarthritis	61 (0.4)	75 (0.5)
Palindromic rheumatism	1 (<0.1)	0
Periarthritis	7 (<0.1)	4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)
Rheumatic disorder	0	1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	3 (<0.1)
Sacroiliitis	1 (<0.1)	0
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)
Spondylitis	2 (<0.1)	0
Synovitis	0	2 (<0.1)
Temporomandibular joint syndrome	5 (<0.1)	2 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Arthritis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.3.4.

Table 72: Participant Incidence of Arthritis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting arthritis events	118 (0.8)	125 (0.8)
Number of arthritis events	124	132
Arthritis	14 (<0.1)	12 (<0.1)
Chondrocalcinosis pyrophosphate	1 (<0.1)	0
Facet joint syndrome	2 (<0.1)	0
Gout	13 (<0.1)	17 (0.1)
Osteoarthritis	61 (0.4)	75 (0.5)
Palindromic rheumatism	1 (<0.1)	0
Periarthritis	7 (<0.1)	4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)
Rheumatic disorder	0	1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	3 (<0.1)
Sacroiliitis	1 (<0.1)	0
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)
Spondylitis	2 (<0.1)	0
Synovitis	0	2 (<0.1)
Temporomandibular joint syndrome	5 (<0.1)	2 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Arthritis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.3.

5.6.5 Convulsion Events

Table 73: Participant Incidence of Convulsion Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting convulsion events	6 (<0.1)	6 (<0.1)
Number of convulsion events	7	6
Aura	1 (<0.1)	0
Seizure	5 (<0.1)	6 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Convulsion events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.7.4.

Table 74: Participant Incidence of Convulsion Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting convulsion events	5 (<0.1)	6 (<0.1)
Number of convulsion events	6	6
Seizure	5 (<0.1)	6 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Convulsion events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.7.

5.6.6 Central Nervous System Vascular Disorder Events

Table 75: Participant Incidence of Central Nervous System Vascular Disorder Events, Narrow and Broad (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting CNS vascular disorder events	22 (0.1)	12 (<0.1)
Number of CNS vascular disorder events	25	13
Aphasia	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	0	1 (<0.1)
Carotid artery stenosis	2 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebral small vessel ischaemic disease	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Embolic stroke	2 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Right hemisphere deficit syndrome	0	1 (<0.1)
Subarachnoid haemorrhage	4 (<0.1)	0
Subdural haematoma	3 (<0.1)	0
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: CNS=central nervous system; MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. CNS vascular disorder events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.10.4.

Table 76: Participant Incidence of Central Nervous System Vascular Disorder Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting CNS vascular disorder events	21 (0.1)	11 (<0.1)
Number of CNS vascular disorder events	24	11
Basal ganglia haemorrhage	0	1 (<0.1)
Carotid artery stenosis	2 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebral small vessel ischaemic disease	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Embolic stroke	2 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Subarachnoid haemorrhage	4 (<0.1)	0
Subdural haematoma	3 (<0.1)	0
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: CNS=central nervous system; MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. CNS vascular disorder events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.10.

5.6.7 Hypersensitivity Events

Table 77: Participant Incidence of Hypersensitivity Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hypersensitivity events	533 (3.5)	505 (3.3)
Number of hypersensitivity events	611	563
Acute respiratory failure	7 (<0.1)	14 (<0.1)
Allergic cough	2 (<0.1)	0
Allergic sinusitis	2 (<0.1)	2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)
Asthma	32 (0.2)	39 (0.3)
Blister	3 (<0.1)	3 (<0.1)
Bronchial hyperreactivity	0	1 (<0.1)
Bronchospasm	3 (<0.1)	1 (<0.1)
Bullous impetigo	0	1 (<0.1)
Choking sensation	1 (<0.1)	0
Conjunctivitis	20 (0.1)	24 (0.2)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Cytokine storm	0	1 (<0.1)
Dermatitis	10 (<0.1)	14 (<0.1)
Dermatitis allergic	3 (<0.1)	5 (<0.1)
Dermatitis atopic	6 (<0.1)	9 (<0.1)
Dermatitis bullous	0	2 (<0.1)
Dermatitis contact	34 (0.2)	41 (0.3)
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eczema	18 (0.1)	11 (<0.1)
Eczema nummular	3 (<0.1)	1 (<0.1)
Eosinophilia	1 (<0.1)	0
Eosinophilic oesophagitis	0	1 (<0.1)
Erythema	17 (0.1)	8 (<0.1)
Exfoliative rash	1 (<0.1)	0
Eye swelling	2 (<0.1)	5 (<0.1)
Flushing	7 (<0.1)	5 (<0.1)
Generalised oedema	1 (<0.1)	0
Hand dermatitis	2 (<0.1)	1 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Incision site rash	1 (<0.1)	0
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	25 (0.2)	1 (<0.1)
Injection site urticaria	38 (0.3)	1 (<0.1)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Mechanical urticaria	1 (<0.1)	0
Mouth ulceration	2 (<0.1)	4 (<0.1)
Neurodermatitis	3 (<0.1)	0
Noninfective conjunctivitis	1 (<0.1)	0
Orbital oedema	0	1 (<0.1)
Oropharyngeal blistering	1 (<0.1)	0
Palatal oedema	0	1 (<0.1)
Perineal rash	1 (<0.1)	0
Perioral dermatitis	1 (<0.1)	3 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Photosensitivity reaction	0	1 (<0.1)
Pneumonitis	0	1 (<0.1)
Pruritus	28 (0.2)	29 (0.2)
Rash	44 (0.3)	47 (0.3)
Rash erythematous	3 (<0.1)	4 (<0.1)
Rash follicular	0	1 (<0.1)
Rash macular	8 (<0.1)	6 (<0.1)
Rash maculo-papular	9 (<0.1)	4 (<0.1)
Rash pruritic	6 (<0.1)	11 (<0.1)
Rash pustular	1 (<0.1)	0
Rash vesicular	2 (<0.1)	1 (<0.1)
Respiratory distress	1 (<0.1)	0
Respiratory failure	2 (<0.1)	1 (<0.1)
Rhinitis allergic	21 (0.1)	26 (0.2)
Seasonal allergy	59 (0.4)	72 (0.5)
Serum sickness	0	1 (<0.1)
Skin exfoliation	1 (<0.1)	1 (<0.1)
Sneezing	22 (0.1)	22 (0.1)
Stomatitis	3 (<0.1)	5 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Throat tightness	0	2 (<0.1)
Type IV hypersensitivity reaction	1 (<0.1)	0
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Vaccination site rash	2 (<0.1)	0
Wheezing	5 (<0.1)	11 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.
Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hypersensitivity events are identified through selected narrow and broad SMQ.
Source: Table 14.3.1.22.2.4.

Table 78: Participant Incidence of Hypersensitivity Events, Narrow Scope, (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hypersensitivity events	336 (2.2)	278 (1.8)
Number of hypersensitivity events	382	301
Allergic cough	2 (<0.1)	0
Allergic sinusitis	2 (<0.1)	2 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)
Bronchospasm	3 (<0.1)	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Dermatitis	10 (<0.1)	14 (<0.1)
Dermatitis allergic	3 (<0.1)	5 (<0.1)
Dermatitis atopic	6 (<0.1)	9 (<0.1)
Dermatitis bullous	0	2 (<0.1)
Dermatitis contact	34 (0.2)	41 (0.3)
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eczema	18 (0.1)	11 (<0.1)
Eczema nummular	3 (<0.1)	1 (<0.1)
Exfoliative rash	1 (<0.1)	0
Eye swelling	2 (<0.1)	5 (<0.1)
Hand dermatitis	2 (<0.1)	1 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Incision site rash	1 (<0.1)	0
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	25 (0.2)	1 (<0.1)
Injection site urticaria	38 (0.3)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Oropharyngeal blistering	1 (<0.1)	0
Palatal oedema	0	1 (<0.1)
Perioral dermatitis	1 (<0.1)	3 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Rash	44 (0.3)	47 (0.3)
Rash erythematous	3 (<0.1)	4 (<0.1)
Rash follicular	0	1 (<0.1)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Rash macular	8 (<0.1)	6 (<0.1)
Rash maculo-papular	9 (<0.1)	4 (<0.1)
Rash pruritic	6 (<0.1)	11 (<0.1)
Rash pustular	1 (<0.1)	0
Rash vesicular	2 (<0.1)	1 (<0.1)
Rhinitis allergic	21 (0.1)	26 (0.2)
Serum sickness	0	1 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	1 (<0.1)	0
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Vaccination site rash	2 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hypersensitivity events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.2.

5.6.8 Peripheral Neuropathy Events

Table 79: Participant Incidence of Peripheral Neuropathy Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting peripheral neuropathy events	82 (0.5)	68 (0.4)
Number of peripheral neuropathy events	98	85
Burning sensation	6 (<0.1)	1 (<0.1)
Dysaesthesia	0	3 (<0.1)
Gait disturbance	0	2 (<0.1)
Hypoaesthesia	17 (0.1)	14 (<0.1)
Muscular weakness	9 (<0.1)	8 (<0.1)
Nerve conduction studies abnormal	1 (<0.1)	0
Neuralgia	3 (<0.1)	5 (<0.1)
Neuropathy peripheral	3 (<0.1)	5 (<0.1)
Paraesthesia	43 (0.3)	31 (0.2)
Peripheral sensory neuropathy	4 (<0.1)	3 (<0.1)
Peroneal nerve palsy	0	2 (<0.1)
Skin burning sensation	3 (<0.1)	1 (<0.1)
Small fibre neuropathy	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Peripheral neuropathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.5.4.

Table 80: Participant Incidence of Peripheral Neuropathy Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting peripheral neuropathy events	12 (<0.1)	13 (<0.1)
Number of peripheral neuropathy events	12	14
Nerve conduction studies abnormal	1 (<0.1)	0
Neuralgia	3 (<0.1)	5 (<0.1)
Neuropathy peripheral	3 (<0.1)	5 (<0.1)
Peripheral sensory neuropathy	4 (<0.1)	3 (<0.1)
Small fibre neuropathy	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Peripheral neuropathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.5.

5.6.9 Demyelination Events

Table 81: Participant Incidence of Demyelination Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting demyelination events	4 (<0.1)	4 (<0.1)
Number of demyelination events	5	4
Hypergammaglobulinaemia benign monoclonal	1 (<0.1)	0
Multiple sclerosis	1 (<0.1)	1 (<0.1)
Optic neuritis	2 (<0.1)	0
Trigeminal neuralgia	1 (<0.1)	3 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Demyelination events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.6.4.

Table 82: Participant Incidence of Demyelination Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting demyelination events	3 (<0.1)	1 (<0.1)
Number of demyelination events	4	1
Hypergammaglobulinaemia benign monoclonal	1 (<0.1)	0
Multiple sclerosis	1 (<0.1)	1 (<0.1)
Optic neuritis	2 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Demyelination events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.6.

5.6.10 Thrombophlebitis Events

Table 83: Participant Incidence of Thrombophlebitis Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting thrombophlebitis events	13 (<0.1)	12 (<0.1)
Number of thrombophlebitis events	13	12
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Phlebitis	1 (<0.1)	2 (<0.1)
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Thrombophlebitis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.14.4.

Table 84: Participant Incidence of Thrombophlebitis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting thrombophlebitis events	3 (<0.1)	4 (<0.1)
Number of thrombophlebitis events	3	4
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Thrombophlebitis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.14.

5.6.11 Vasculitis Events

Table 85: Participant Incidence of Vasculitis Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting vasculitis events	1 (<0.1)	1 (<0.1)
Number of vasculitis events	1	1
Polyarteritis nodosa	1 (<0.1)	0
Polymyalgia rheumatica	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Vasculitis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.1.4.

Table 86: Participant Incidence of Vasculitis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting vasculitis events	1 (<0.1)	1 (<0.1)
Number of vasculitis events	1	1
Polyarteritis nodosa	1 (<0.1)	0
Polymyalgia rheumatica	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Vasculitis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.1.

5.6.12 Hematopoietic Cytopenia Events

Table 87: Participant Incidence of Hematopoietic Cytopenia Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hematopoietic cytopenia events	32 (0.2)	20 (0.1)
Number of hematopoietic cytopenia events	33	20
Anaemia	21 (0.1)	17 (0.1)
Anaemia macrocytic	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	0
Leukopenia	2 (<0.1)	0
Lymphocyte count decreased	1 (<0.1)	0
Normocytic anaemia	2 (<0.1)	1 (<0.1)
Thrombocytopenia	5 (<0.1)	1 (<0.1)
White blood cell count decreased	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hematopoietic cytopenia events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.15.4.

Table 88: Participant Incidence of Hematopoietic Cytopenia Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hematopoietic cytopenia events	9 (<0.1)	2 (<0.1)
Number of hematopoietic cytopenia events	9	2
Anaemia macrocytic	0	1 (<0.1)
Leukopenia	2 (<0.1)	0
Lymphocyte count decreased	1 (<0.1)	0
Thrombocytopenia	5 (<0.1)	1 (<0.1)
White blood cell count decreased	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hematopoietic cytopenia events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.15.

5.6.13 Cardiomyopathy Events

5.6.13.1 Overall and by Age Group

5.6.13.1.1 Overall

Table 89: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	207 (1.4%)	208 (1.4%)
Number of cardiomyopathy events	238	254
Acute left ventricular failure	2 (<0.1%)	2 (<0.1%)
Arrhythmia	5 (<0.1%)	8 (0.1%)
Ascites	0 (0.00%)	2 (<0.1%)
Atrial enlargement	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic decreased	0 (0.00%)	2 (<0.1%)
Blood pressure diastolic increased	13 (0.1%)	10 (0.1%)
Blood pressure systolic abnormal	1(<0.1%)	1 (<0.1%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.00%)
Blood pressure systolic increase	21 (0.1%)	21 (0.1%)
Cardiac arrest	1 (<0.1%)	0 (0.00%)
Cardiac failure	4 (<0.1%)	4 (<0.1%)
Cardiac failure acute	1 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	6 (<0.1%)	9 (0.1%)
Cardiomegaly	0 (0.00%)	2 (<0.1%)
Cardiomyopathy	2 (<0.1%)	1 (<0.1%)
Chest pain	15 (0.1%)	11 (0.1%)
Diastolic dysfunction	0 (0.00%)	1 (<0.1%)
Dyspnoea	92 (0.6%)	86 (0.6%)
Left atrial enlargement	0 (0.00%)	1 (<0.1%)
Lung opacity	0 (0.00%)	2 (<0.1%)
Mental status changes	1 (<0.1%)	4 (<0.1%)
Nocturia	4 (<0.1%)	1 (<0.1%)
Oedema	0 (0.00%)	1 (<0.1%)
Orthostatic hypotension	6 (<0.1%)	1 (<0.1%)
Palpitations	22 (0.1%)	13 (0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.00%)
Syncope	25 (0.2%)	40 (0.3%)
Ventricular arrhythmia	0 (0.00%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4.

Table 90: Participant Incidence of Cardiomyopathy Events, Narrow Scope, All Participants Overall (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	3 (<0.1%)	1 (<0.1%)
Number of cardiomyopathy events	3	1
Cardiomyopathy	2 (<0.1%)	1 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16.

5.6.13.1.2 Overall Males

Table 91: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall Males (Safety Set)

Preferred Term	mRNA-1273 (N=7918) n (%)	Placebo (N=8056) n (%)
Number of participants reporting cardiomyopathy events	107 (1.4%)	100 (1.2%)
Number of cardiomyopathy events	122	121
Acute left ventricular failure	2 (<0.1%)	1 (<0.1%)
Arrhythmia	5 (0.1%)	6 (0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Atrial enlargement	1 (<0.1%)	0 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	8 (0.1%)	4 (<0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	8 (0.1%)	10 (0.1%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	2 (<0.1%)	3 (<0.1%)
Cardiac failure acute	1 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	2 (<0.1%)	5 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	2 (<0.1%)	0 (0.0%)
Chest pain	10 (0.1%)	5 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	41 (0.5%)	37 (0.5%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	1 (<0.1%)	4 (<0.1%)
Nocturia	4 (0.1%)	1 (<0.1%)
Orthostatic hypotension	3 (<0.1%)	1 (<0.1%)
Palpitations	14 (0.2%)	4 (<0.1%)
Syncope	15 (0.2%)	23 (0.3%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

5.6.13.1.3 Overall Females

Table 92: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall Females (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	100 (1.4%)	108 (1.5%)
Number of cardiomyopathy events	116	134
Acute left ventricular failure	0 (0.0%)	1 (<0.1%)
Arrhythmia	3 (<0.1%)	6 (0.1%)
Atrial enlargement	0 (0.0%)	0 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	5 (0.1%)	4 (0.1%)
Blood pressure systolic abnormal	1 (<0.1%)	1 (<0.1%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.00%)
Blood pressure systolic increase	13 (0.2%)	11 (0.2%)
Cardiac failure	2 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	4 (0.1%)	4 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	0 (0.0%)	1 (<0.1%)
Chest pain	5 (0.1%)	6 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	51 (0.7%)	48 (0.7%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	0 (0.0%)	4 (0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	3 (<0.1%)	1 (<0.1%)
Palpitations	8 (0.1%)	9 (0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	10 (0.1%)	17 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

5.6.13.1.4 Ages 18 to 30 Years

Table 93: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=1759) n (%)	Placebo (N=1755) n (%)
Number of participants reporting cardiomyopathy events	18 (1.0%)	24 (1.4%)
Number of cardiomyopathy events	21	26
Blood pressure diastolic decreased	0 (0.0%)	1 (0.1%)
Blood pressure diastolic increased	0 (0.0%)	2 (0.1%)
Chest pain	2 (0.1%)	3 (0.2%)
Dyspnoea	8 (0.5%)	8 (0.5%)
Orthostatic hypotension	1 (0.1%)	0 (0.0%)
Palpitations	2 (0.1%)	2 (0.1%)
Syncope	5 (0.3%)	8 (0.5%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 94: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=1759) n (%)	Placebo (N=1755) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.1.5 Ages > 30 to < 60 Years

Table 95: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=8069) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	104 (1.3%)	96 (1.2%)
Number of cardiomyopathy events	121	120
Acute left ventricular failure	1 (<0.1%)	0 (0.0%)
Arrhythmia	1 (<0.1%)	4 (<0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Blood pressure diastolic increased	10 (0.1%)	6 (0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	9 (0.1%)	8 (0.1%)
Cardiac failure	1 (<0.1%)	0 (0.0%)
Cardiac failure acute	1 (<0.1%)	0 (0.0%)
Cardiac failure congestive	0 (0.0%)	3 (<0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	1 (<0.1%)
Chest pain	8 (0.1%)	5 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	57 (0.7%)	46 (0.6%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	0 (0.0%)	2 (<0.1%)
Nocturia	1 (<0.1%)	0 (0.0%)
Orthostatic hypotension	1 (<0.1%)	0 (0.0%)
Palpitations	12 (0.1%)	9 (0.1%)
Syncope	9 (0.1%)	13 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 96: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=8069) n (%)	Placebo (N=8065) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	1 (<0.1%)
Number of cardiomyopathy events	1	1
Cardiomyopathy	1 (<0.1%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.1.6 Ages ≥ 60 Years

Table 97: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=5356) n (%)	Placebo (N=5342) n (%)
Number of participants reporting cardiomyopathy events	85 (1.6%)	88 (1.6%)
Number of cardiomyopathy events	96	109
Acute left ventricular failure	1 (<0.1%)	2 (<0.1%)
Arrhythmia	4 (0.1%)	4 (0.1%)
Atrial enlargement	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	3 (0.1%)	2 (<0.1%)
Blood pressure systolic abnormal	1 (<0.1%)	0 (0.0%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.0%)
Blood pressure systolic increase	12 (0.2%)	13 (0.2%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	3 (0.1%)	4 (0.1%)
Cardiac failure acute	0 (0.0%)	1 (<0.1%)
Cardiac failure congestive	6 (0.1%)	6 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	5 (0.1%)	3 (0.1%)
Dyspnoea	26 (0.5%)	32 (0.6%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Mental status changes	1 (<0.1%)	2 (<0.1%)
Nocturia	3 (0.1%)	1 (<0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	4 (0.1%)	1 (<0.1%)
Palpitations	7 (0.1%)	2 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	11 (0.2%)	19 (0.4%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 98: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=5356) n (%)	Placebo (N=5342) n (%)
Number of participants reporting cardiomyopathy events	2 (<0.1%)	0 (0%)
Number of cardiomyopathy events	2	0
Cardiomyopathy	1 (<0.1%)	0 (0%)
Stress cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2 By Gender and Age Group

5.6.13.2.1 Male Participants

5.6.13.2.1.1 Males Ages 18 to 30 Years

Table 99: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=875) n (%)	Placebo (N=911) n (%)
Number of participants reporting cardiomyopathy events	7 (0.8%)	10 (1.1%)
Number of cardiomyopathy events	7	12
Chest pain	2 (0.2%)	2 (0.2%)
Dyspnoea	2 (0.2%)	4 (0.4%)
Orthostatic hypotension	1 (0.1%)	0 (0.0%)
Palpitations	1 (0.1%)	0 (0.0%)
Syncope	1 (0.1%)	4 (0.4%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 100: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=875) n (%)	Placebo (N=911) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.1.2 Males Ages > 30 to < 60 Years

Table 101: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=4206) n (%)
Number of participants reporting cardiomyopathy events	60 (1.5%)	47 (1.1%)
Number of cardiomyopathy events	68	57
Acute left ventricular failure	1 (<0.1%)	0 (0.0%)
Arrhythmia	0 (0.0%)	3 (0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Blood pressure diastolic increased	7 (0.2%)	2 (<0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	5 (0.1%)	4 (0.1%)
Cardiac failure	1 (<0.1%)	0 (0.0%)
Cardiac failure acute	1 (<0.1%)	0 (0.0%)
Cardiac failure congestive	0 (0.0%)	2 (<0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	7 (0.2%)	3 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	26 (0.7%)	21 (0.5%)
Nocturia	1 (<0.1%)	0 (0.0%)
Orthostatic hypotension	1 (<0.1%)	0 (0.0%)
Palpitations	9 (0.2%)	3 (0.1%)
Syncope	6 (0.2%)	8 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 102: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=4206) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.1.3 Males Ages ≥ 60 Years

Table 103: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2904) n (%)	Placebo (N=2939) n (%)
Number of participants reporting cardiomyopathy events	40 (1.4%)	44 (1.5%)
Number of cardiomyopathy events	47	53
Acute left ventricular failure	1 (<0.1%)	1 (<0.1%)
Arrhythmia	2 (0.1%)	3 (0.1%)
Atrial enlargement	1 (<0.1%)	0 (0.0%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	1 (<0.1%)	2 (0.1%)
Blood pressure systolic increase	3 (0.1%)	6 (0.2%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	1 (<0.1%)	3 (0.1%)
Cardiac failure acute	0 (0.0%)	1 (<0.1%)
Cardiac failure congestive	2 (0.1%)	3 (0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	1 (<0.1%)	1 (<0.1%)
Dyspnoea	13 (0.4%)	12 (0.4%)
Mental status changes	1 (<0.1%)	0 (0.0%)
Nocturia	2 (0.1%)	1 (<0.1%)
Orthostatic hypotension	1 (<0.1%)	1 (<0.1%)
Palpitations	4 (0.1%)	1 (<0.1%)
Syncope	8 (0.3%)	11 (0.4%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 104: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2904) n (%)	Placebo (N=2939) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2 Female Participants

5.6.13.2.2.1 Females Ages 18 to 30 Years

Table 105: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=884) n (%)	Placebo (N=844) n (%)
Number of participants reporting cardiomyopathy events	10 (1.1%)	14 (1.7%)
Number of cardiomyopathy events	14	14
Blood pressure diastolic decreased	0 (0.0%)	1 (0.1%)
Blood pressure diastolic increased	0 (0.0%)	2 (0.2%)
Chest pain	0 (0.0%)	1 (0.1%)
Dyspnoea	7 (0.8%)	4 (0.5%)
Palpitations	1 (0.1%)	2 (0.2%)
Syncope	4 (0.5%)	4 (0.5%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 106: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=884) n (%)	Placebo (N=844) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2.2 Females Ages > 30 to < 60 Years

Table 107: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=3859) n (%)
Number of participants reporting cardiomyopathy events	44 (1.1%)	50 (1.3%)
Number of cardiomyopathy events	53	64
Arrhythmia	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic increased	3 (0.1%)	4 (0.1%)
Blood pressure systolic increase	4 (0.1%)	4 (0.1%)
Cardiac failure congestive	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	0 (0.0%)	1 (<0.1%)
Chest pain	1 (<0.1%)	3 (0.1%)
Dyspnoea	31 (0.8%)	25 (0.6%)
Lung opacity	0 (0.0%)	1 (<0.1%)
Mental status changes	0 (0.0%)	1 (<0.1%)
Palpitations	4 (0.1%)	3 (0.1%)
Syncope	3 (0.1%)	5 (0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 108: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=3859) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2.3 Females Ages ≥ 60 Years

Table 109: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2452) n (%)	Placebo (N=2403) n (%)
Number of participants reporting cardiomyopathy events	45 (1.8%)	44 (1.8%)
Number of cardiomyopathy events	49	56
Acute left ventricular failure	0 (0.0%)	1 (<0.1%)
Arrhythmia	2 (0.1%)	1 (<0.1%)
Atrial enlargement	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	2 (0.1%)	0 (0.0%)
Blood pressure systolic abnormal	1 (<0.1%)	0 (0.0%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.0%)
Blood pressure systolic increase	9 (0.4%)	7 (0.3%)
Cardiac failure	2 (0.1%)	1 (<0.1%)
Cardiac failure congestive	4 (0.2%)	3 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Chest pain	4 (0.2%)	2 (0.1%)
Dyspnoea	13 (0.5%)	19 (0.8%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Mental status changes	0 (0.0%)	2 (0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	3 (0.1%)	0 (0.0%)
Palpitations	3 (0.1%)	1 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	3 (0.1%)	8 (0.3%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 110: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2452) n (%)	Placebo (N=2403) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Stress cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).