

US3142268 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:21:56

All time stamps listed in this document are displayed in GMT

US3142268

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:38:39

Generated On: 09 Jun 2021 15:21:56

Participant ID

US3142268

[mRNA-1273-P301 Completion Guidelines](#)

US3142268

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Date of Informed Consent (<i>dd MMM yyyy</i>)	4 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 21:46:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 21:46:50

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Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	IBS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	TESTICULAR CANCER
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3142268

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:36
Height (xxx.x)	76 in
Weight (xxx.x)	251.2 lb
BMI (xxx.x)	30.64096 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:46:50

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☒ No ☐

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:46:50

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111840

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Height	ND - Not Done
Weight	ND - Not Done

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:36
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:50
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG

US3142268

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:20 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:20

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	14:56 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:56

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:56	4 SEP 2020 14:56
Nasopharyngeal Swab 2	Yes	14:56	4 SEP 2020 14:56

US3142268

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 15:40

PC Close Date & Time

04 SEP 2020 18:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 19:05

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

05 SEP 2020 23:36

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

06 SEP 2020 15:28

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

07 SEP 2020 14:45

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 SEP 2020 19:51

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

09 SEP 2020 16:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 15:40

PC Close Date & Time

04 SEP 2020 18:10

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 19:05

PC Close Date & Time

05 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 23:37

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 15:29

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 14:45

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:51

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 15:40

PC Close Date & Time

04 SEP 2020 18:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 19:05

PC Close Date & Time

05 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION (doctor visit,
other)** for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:38
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:29
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 14:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3142268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:50
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3142268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 SEP 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 16:20

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3142268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

16:17 (24 HR)

Collection date and time (derived)

30 SEP 2020 16:17

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	30 SEP 2020 16:10
Nasopharyngeal Swab 2	No		

US3142268

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 SEP 2020 16:53

PC Open Date & Time

30 SEP 2020 16:40

PC Close Date & Time

30 SEP 2020 19:10

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	01 OCT 2020 06:31
PC Open Date & Time	30 SEP 2020 20:05
PC Close Date & Time	01 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 OCT 2020 18:16

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 OCT 2020 14:40

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

03 OCT 2020 15:39

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

04 OCT 2020 18:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

05 OCT 2020 14:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 16:53

PC Open Date & Time

30 SEP 2020 16:40

PC Close Date & Time

30 SEP 2020 19:10

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 06:31

PC Open Date & Time

30 SEP 2020 20:05

PC Close Date & Time

01 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 18:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 14:41

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 15:39

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 18:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 14:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 16:54
PC Open Date & Time	30 SEP 2020 16:40
PC Close Date & Time	30 SEP 2020 19:10

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 06:32
PC Open Date & Time	30 SEP 2020 20:05
PC Close Date & Time	01 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:17
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:42
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 15:40
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:31
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☐

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3142268

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	16 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

16 OCT 2020 14:50

US3142268

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	27 DEC 2020 00:01
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Patient Cloud Close Date & Time	31 DEC 2020 23:59
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US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 MAY 2021 13:36:55

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2022 00:01
Patient Cloud Close Date & Time	19 MAY 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	23 OCT 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3142268

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:21:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAY 2021 13:36:19

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:46:50

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

SUBJECT IS NOW TAKING
PROTANIX 40MG A DAY FOR
AN ULCER

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3142268

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3142268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 MAR 2021

Collection time (00:00-23:59)

16:21 (24 HR)

Collection date and time (derived)

18 MAR 2021 16:21

US3142268

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:46:51

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142268

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact Contact Made ☐
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142268

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142268

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:21:56

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3142268

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:21:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Date of updated informed consent (*dd MMM yyyy*) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

09:22 (24 HR)

Collection date and time (derived)

15 JAN 2021 09:22

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	09:23
Collection Date and Time (derived)	15 JAN 2021 09:23

US3142268

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 21:38:39

Generated On: 09 Jun 2021 15:21:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:45:56

Generated On: 09 Jun 2021 15:21:56

AEID	USA-US064-2020-MRNA-1273-P30 1000003
Adverse event	DUODENAL ULCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	23 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:45:56

Generated On: 09 Jun 2021 15:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:45:56

Generated On: 09 Jun 2021 15:21:56

SUBJECT HOSPITALIZED DUE
TO WORSENING NAUSEA.
SUBJECT HAD ENDOSCOPY
DONE 23 OCTOBER 2020 WHICH
REVEALED A DUODENAL
ULCER.
SUBJECT HAD NEGATIVE
COVID TEST 23OCT2020.
SUBJECT GIVEN 3 UNITS OF
PRBC DURING THE COURSE OF
HOSPITALIZATION. SUBJECT'S
HEMOGLOBIN DROPPED FROM
13.9 G/DL TO 8.2 G/DL DURING
THE COURSE OF
HOSPITALIZATION. SUBJECT
HAD CT ABDOMEN/PELVIS AND
AN EGD AND COLONOSCOPY
23OCT2020. EGD FINDINGS
WERE SIGNIFICANT FOR 2 CM
ULCER IN THE DUODENAL
BULB WITH CLOT PRESENT.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3142268

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 02:45:56

Generated On: 09 Jun 2021 15:21:56

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3142268

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 02:45:56

Generated On: 09 Jun 2021 15:21:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 21:38:40

Generated On: 09 Jun 2021 15:21:56

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SPRAY

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication FORTESTA

Prophylaxis Yes ☐
No ☒

Indication HYPOGONADISM

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication VITAMIN B-12

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN AFTER
SECOND VACCINATION

Dose per administration 975

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT NEAUSEA

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication DUODENAL ULCER

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication VITAMIN B6

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATIONS

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication UNSPECIFIED PAIN

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS DEHYDRATION

Dose per administration 500

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Name of Medication PANTOPRAZOLE SODIUM

Prophylaxis Yes ☐
No ☒

Indication ULCER

Dose per administration 250

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 OCT 2020	CT ABDOMEN AND PELVIS WITH CONTRAST	Adverse Event	
23 OCT 2020	EGD	Adverse Event	
23 OCT 2020	COLONOSCOPY	Adverse Event	

US3142268

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:21:56

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3142268

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:21:56

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/OCT/2020 16:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/NOV/2020 12:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/NOV/2020 12:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/FEB/2021 12:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/MAR/2021 06:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 02:45:57

Generated On: 09 Jun 2021 15:21:56

SAEID	USA-US064-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/APR/2021 07:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142268 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142268

Form: Participant Creation

Generated On: 09 Jun 2021 15:21:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:37:18
User entered 'US3142268'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:29:19

US3142268

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:27:59
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:37:30

US3142268

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:28:01
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:29:20

US3142268

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:03
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	04 Sep 2020 22:37:30

US3142268

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'SCRN'	System	04 Sep 2020 22:37:30

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '(b) (6)1960'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:29:21

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '60'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'YEARS'	System	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '60'	System	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered 'Male (M)'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered 'I'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:21:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:28:52
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:37:57

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Sep 2020'	System	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2020'	System	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:29:21
DataPoint Un-verified.	Meghan York (b) (4)	09 Dec 2020 23:50:05
User entered 'Amendment 3 (3)' reason for change:	Meghan York (b) (4)	09 Dec 2020 23:50:05
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered 'Amendment 1 (1)'	Meghan York (b) (4)	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:38:10

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:38:10

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:29:14
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:29:20

US3142268

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:21:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'I'	System	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:21:56

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:28:07
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:21:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:21
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:38:25

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:50
Data point term sent to Coder	System	04 Sep 2020 22:39:57
User entered 'cataracts'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 2012'	Meghan York (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 2012'	Meghan York (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 2012'	System	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2012'	System	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 2012'	System	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2012'	System	04 Sep 2020 22:39:03

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:49
Data point term sent to Coder	System	04 Sep 2020 22:39:57
User entered 'seasonal allergies'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 1995'	Meghan York (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 1995'	System	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '1995'	System	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:39:33

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:40:49
Data point term sent to Coder	System	04 Sep 2020 22:39:59
User entered 'ibs'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 2015'	Meghan York (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 2015'	System	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2015'	System	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:39:52

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:41:50
Data point term sent to Coder	System	04 Sep 2020 22:40:59
User entered 'back pain'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 2000'	Meghan York (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 2000'	System	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2000'	System	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:40:20

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:41:50
Data point term sent to Coder	System	04 Sep 2020 22:40:59
User entered 'migraines'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 1972'	Meghan York (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 1972'	System	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '1972'	System	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:40:52

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		02 Nov 2020 02:21:22
Query 'Per DM CLR: Please note that there is no Con Meghan York Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Subject did not specify any medication for this condition ' (Site from DM).	(b) (4) (b) (4)	23 Oct 2020 17:05:00
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 00:52:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:42:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:42:51
Data point term sent to Coder	System	04 Sep 2020 22:42:00
User entered 'high blood pressure'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 2015'	Meghan York (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 2015'	System	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '2015'	System	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	04 Sep 2020 22:41:19

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Testicular neoplasms malignant, PT: Testis cancer, LLT: Testicular cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:42:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:42:51
Data point term sent to Coder	System	04 Sep 2020 22:42:01
User entered 'testicular cancer'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 1997'	Meghan York (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'UN UNK 1997'	Meghan York (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 1997'	System	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '1997'	System	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'Jan 1997'	System	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '1997'	System	04 Sep 2020 22:41:56

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:03:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:03:31
Data point term sent to Coder	System	23 Oct 2020 17:02:48
User entered 'HYPOGONADISM'	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'I'	Meghan York (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered empty.	Meghan York (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:47
User entered '0'	Meghan York (b) (4)	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:21:56

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered empty.	System	23 Oct 2020 17:02:48

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered 'Yes (Y)'	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered '4 Sep 2020'	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered '14:36'	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '4 Sep 2020 14:36'	System	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered '76' in	Meghan York (b) (4)	15 Sep 2020 19:39:46
DataPoint set to visible.	(b) (4) System	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered '251.2' lb	Meghan York (b) (4)	15 Sep 2020 19:39:46
DataPoint set to visible.	(b) (4) System	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered '30.64096'	System	15 Sep 2020 19:39:46
DataPoint set to visible.	System	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'kg/m2'	System	15 Sep 2020 19:39:46
DataPoint set to visible.	System	04 Sep 2020 22:38:15

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered missing code ND - Not Done.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered empty.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered empty.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered missing code ND - Not Done.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'bpm'	System	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered missing code ND - Not Done.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'breaths/min'	System	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered missing code ND - Not Done.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'mmHg'	System	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:01
User entered missing code ND - Not Done.	Meghan York (b) (4)	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User entered 'mmHg'	System	15 Sep 2020 19:39:46

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42

US3142268

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42

US3142268

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:09
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:42:50

US3142268

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:11
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:42:50

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:35
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:38
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:40
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:42
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:36:49
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:51
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:36:54
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:01
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:05
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:13
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:18
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:21
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:57
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
User entered 'I'	(b) (4) Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:39
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:41
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:43
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:45
User entered '0'	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:37:47
User entered '0'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
User entered '0'	(b) (4) Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:21:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:39:42
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:37:51
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:43:16

US3142268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:32:46
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:43:29
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:32:48
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:43:29
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:32:50
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	04 Sep 2020 22:43:29
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'VISIT1'	System	04 Sep 2020 22:43:29

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:31
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:09:40

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:34
User entered '111840'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:09:40

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:36
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 21:09:40

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:39
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:40
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:46
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:40
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:50
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:40
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:53
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:40
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:56
User entered 'No (N)'	Meghan York (b) (4)	04 Sep 2020 22:43:40
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:21:56

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:03:54
User closed query 'Per CDM: Subject was randomized under Amendment 3 or higher however HIV status is not provided. Please enter ' (Site from DM).		22 Apr 2021 08:20:14
Query 'Per CDM: Subject was randomized under Amendment 3 or higher however HIV status is not provided. Please enter ' answered with 'corrected' (Site from DM).	Jill York (b) (4)	21 Apr 2021 17:18:58
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:18:52
User opened query 'Per CDM: Subject was randomized under Amendment 3 or higher however HIV status is not provided. Please enter ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 01:56:51
DataPoint set to visible.	System	09 Dec 2020 23:50:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:30:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:24
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:26
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:24
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:26
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '14:36'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 14:36'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '97.9' F	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'Other (Other)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'temporal'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '92'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'bpm'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '16'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'breaths/min'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '146'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'mmHg'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '92'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'mmHg'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:24
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:21:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:35:26
User entered missing code ND - Not Done.	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '15:50'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 15:50'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '96.8' F	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'Other (Other)'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered 'temporal'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '89'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'bpm'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '13'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'breaths/min'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
User entered '146'	Meghan York (b) (4)	04 Sep 2020 22:54:42
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'mmHg'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:35:36
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		17 Sep 2020 00:29:13
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		04 Sep 2020 22:54:42
User entered '109'	Meghan York (b) (4) (b) (4)	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'mmHg'	System	04 Sep 2020 22:54:42

US3142268

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:36:12
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4)	29 Sep 2020 15:33:33
	(b) (4)	
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:54:54
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:36:12
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	29 Sep 2020 15:33:33
	(b) (4)	
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:54:54
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:19
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:20
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:22
User entered empty.	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 22:55:18

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:24
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:36:28
User entered '15:20'	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 15:20'	System	04 Sep 2020 22:55:18

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:26
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	04 Sep 2020 22:55:18
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
DataPoint Verified.		11 Nov 2020 20:43:31
User entered 'ONCE'	System	04 Sep 2020 22:55:18

US3142268

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 22:55:18

US3142268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:52
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:55:38
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:56
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:55:38
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:43:58
User entered '14:56'	Meghan York (b) (4)	04 Sep 2020 22:55:38
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 14:56'	System	04 Sep 2020 22:55:38

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:21:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:44:16
User entered '4 Sep 2020'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:13
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:13
User entered '14:56'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 14:56'	System	04 Sep 2020 22:55:56

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:13
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:13
User entered '14:56'	Meghan York (b) (4)	04 Sep 2020 22:55:56
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '4 Sep 2020 14:56'	System	04 Sep 2020 22:55:56

US3142268

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:37:22
User entered 'Yes (Y)'	Meghan York (b) (4)	04 Sep 2020 22:56:01
	(b) (4)	

US3142268

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered '1'	System	04 Sep 2020 22:56:01

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 15:40'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 18:10'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 2'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:36:28', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '78c98407-58a3-4bad-b6a8-b0abc8bf0270'	System	06 Sep 2020 05:36:58
User entered 'Yes (Y)'	System	06 Sep 2020 05:36:58

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:36:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '78c98407-58a3-4bad-b6a8-b0abc8bf0270' User entered '97.9'	System	06 Sep 2020 05:36:58
	System	06 Sep 2020 05:36:58

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:36:47', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '78c98407-58a3-4bad-b6a8-b0abc8bf0270' User entered 'No (N)'	System	06 Sep 2020 05:36:58
	System	06 Sep 2020 05:36:58

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:36:55', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '78c98407-58a3-4bad-b6a8-b0abc8bf0270' User entered '05 Sep 2020 23:36'	System	06 Sep 2020 05:36:58
	System	06 Sep 2020 05:36:58

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 3'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:28:37', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e42b979d-c25b-41e0-a338-704c8ae0e12d' User entered 'Yes (Y)'	System	06 Sep 2020 21:29:00
	System	06 Sep 2020 21:29:00

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:28:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e42b979d-c25b-41e0-a338-704c8ae0e12d' User entered '96.4'	System	06 Sep 2020 21:29:00
	System	06 Sep 2020 21:29:00

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:28:50', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e42b979d-c25b-41e0-a338-704c8ae0e12d' User entered 'No (N)'	System	06 Sep 2020 21:29:00
	System	06 Sep 2020 21:29:00

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:28:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e42b979d-c25b-41e0-a338-704c8ae0e12d' User entered '06 Sep 2020 15:28'	System	06 Sep 2020 21:29:00
	System	06 Sep 2020 21:29:00

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 4'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:44:55', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'acfd1737-528f-4e60-af6e-028ee2541bba' User entered 'Yes (Y)'	System	07 Sep 2020 20:45:14
	System	07 Sep 2020 20:45:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:04', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'acfd1737-528f-4e60-af6e-028ee2541bba' User entered '97.4'	System	07 Sep 2020 20:45:14
	System	07 Sep 2020 20:45:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'acfd1737-528f-4e60-af6e-028ee2541bba'	System	07 Sep 2020 20:45:14
User entered 'No (N)'	System	07 Sep 2020 20:45:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:11', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'acfd1737-528f-4e60-af6e-028ee2541bba'	System	07 Sep 2020 20:45:14
User entered '07 Sep 2020 14:45'	System	07 Sep 2020 20:45:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 5'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd7285770-5ebe-43b0-81f4-c5907949b767' User entered 'Yes (Y)'	System	09 Sep 2020 01:51:20
	System	09 Sep 2020 01:51:20

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:07', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd7285770-5ebe-43b0-81f4-c5907949b767' User entered '97.4'	System	09 Sep 2020 01:51:20
	System	09 Sep 2020 01:51:20

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:09', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd7285770-5ebe-43b0-81f4-c5907949b767'	System	09 Sep 2020 01:51:20
User entered 'No (N)'	System	09 Sep 2020 01:51:20

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:15', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd7285770-5ebe-43b0-81f4-c5907949b767' User entered '08 Sep 2020 19:51'	System	09 Sep 2020 01:51:20
	System	09 Sep 2020 01:51:20

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 6'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd2486c03-2c24-4fb8-8319-2a6eaa445fc5'	System	09 Sep 2020 22:19:30
User entered 'Yes (Y)'	System	09 Sep 2020 22:19:30

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:21', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd2486c03-2c24-4fb8-8319-2a6eaa445fc5' User entered '97.8'	System	09 Sep 2020 22:19:30
	System	09 Sep 2020 22:19:30

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:24', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd2486c03-2c24-4fb8-8319-2a6eaa445fc5'	System	09 Sep 2020 22:19:30
User entered 'No (N)'	System	09 Sep 2020 22:19:30

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:28', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd2486c03-2c24-4fb8-8319-2a6eaa445fc5'	System	09 Sep 2020 22:19:30
User entered '09 Sep 2020 16:19'	System	09 Sep 2020 22:19:30

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 7'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 15:40'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 18:10'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 2'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'ba54fd77-ad2e-4309-ad1f-7a4892f5796a' User entered 'None (1)'	System	06 Sep 2020 05:37:28
	System	06 Sep 2020 05:37:28

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'ba54fd77-ad2e-4309-ad1f-7a4892f5796a'	System	06 Sep 2020 05:37:28
User entered 'No (N)'	System	06 Sep 2020 05:37:28

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:12', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'ba54fd77-ad2e-4309-ad1f-7a4892f5796a'	System	06 Sep 2020 05:37:28
User entered 'No (N)'	System	06 Sep 2020 05:37:28

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'ba54fd77-ad2e-4309-ad1f-7a4892f5796a'	System	06 Sep 2020 05:37:28
User entered 'None (1)'	System	06 Sep 2020 05:37:28

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:23', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'ba54fd77-ad2e-4309-ad1f-7a4892f5796a' User entered '05 Sep 2020 23:37'	System	06 Sep 2020 05:37:28
	System	06 Sep 2020 05:37:28

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 3'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:07', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '7eae227c-90bd-40d8-b34a-0b2d7370e50f' User entered 'None (1)'	System	06 Sep 2020 21:29:22
	System	06 Sep 2020 21:29:22

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:10', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '7eae227c-90bd-40d8-b34a-0b2d7370e50f' User entered 'No (N)'	System	06 Sep 2020 21:29:22
	System	06 Sep 2020 21:29:22

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:14', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '7eae227c-90bd-40d8-b34a-0b2d7370e50f' User entered 'No (N)'	System	06 Sep 2020 21:29:22
	System	06 Sep 2020 21:29:22

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:17', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '7eae227c-90bd-40d8-b34a-0b2d7370e50f' User entered 'None (1)'	System	06 Sep 2020 21:29:22
	System	06 Sep 2020 21:29:22

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '7eae227c-90bd-40d8-b34a-0b2d7370e50f' User entered '06 Sep 2020 15:29'	System	06 Sep 2020 21:29:22
	System	06 Sep 2020 21:29:22

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 4'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '3e5a1605-23d6-4cb1-acc1-b0688c5bd913'	System	07 Sep 2020 20:45:34
User entered 'None (1)'	System	07 Sep 2020 20:45:34

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:19', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '3e5a1605-23d6-4cb1-acc1-b0688c5bd913' User entered 'No (N)'	System	07 Sep 2020 20:45:34
	System	07 Sep 2020 20:45:34

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:23', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '3e5a1605-23d6-4cb1-acc1-b0688c5bd913' User entered 'No (N)'	System	07 Sep 2020 20:45:34
	System	07 Sep 2020 20:45:34

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:26', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '3e5a1605-23d6-4cb1-acc1-b0688c5bd913' User entered 'None (1)'	System	07 Sep 2020 20:45:34
	System	07 Sep 2020 20:45:34

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:30', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '3e5a1605-23d6-4cb1-acc1-b0688c5bd913' User entered '07 Sep 2020 14:45'	System	07 Sep 2020 20:45:34
	System	07 Sep 2020 20:45:34

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 5'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '99c98d96-5fc9-484d-becb-8904cf2141a2'	System	09 Sep 2020 01:51:38
User entered 'None (1)'	System	09 Sep 2020 01:51:38

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:24', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '99c98d96-5fc9-484d-becb-8904cf2141a2'	System	09 Sep 2020 01:51:38
User entered 'No (N)'	System	09 Sep 2020 01:51:38

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:28', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '99c98d96-5fc9-484d-becb-8904cf2141a2'	System	09 Sep 2020 01:51:38
User entered 'No (N)'	System	09 Sep 2020 01:51:38

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:32', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '99c98d96-5fc9-484d-becb-8904cf2141a2' User entered 'None (1)'	System	09 Sep 2020 01:51:38
	System	09 Sep 2020 01:51:38

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:36', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '99c98d96-5fc9-484d-becb-8904cf2141a2' User entered '08 Sep 2020 19:51'	System	09 Sep 2020 01:51:38
	System	09 Sep 2020 01:51:38

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 6'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:33', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '8b5237a4-3ce4-4615-9fdc-de128bd44bd9'	System	09 Sep 2020 22:19:47
User entered 'None (1)'	System	09 Sep 2020 22:19:47

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:36', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '8b5237a4-3ce4-4615-9fdc-de128bd44bd9' User entered 'No (N)'	System	09 Sep 2020 22:19:47
	System	09 Sep 2020 22:19:47

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:38', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '8b5237a4-3ce4-4615-9fdc-de128bd44bd9' User entered 'No (N)'	System	09 Sep 2020 22:19:47
	System	09 Sep 2020 22:19:47

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:42', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '8b5237a4-3ce4-4615-9fdc-de128bd44bd9' User entered 'None (1)'	System	09 Sep 2020 22:19:47
	System	09 Sep 2020 22:19:47

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '8b5237a4-3ce4-4615-9fdc-de128bd44bd9' User entered '09 Sep 2020 16:19'	System	09 Sep 2020 22:19:47
	System	09 Sep 2020 22:19:47

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 7'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 15:40'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 18:10'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 2'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:36', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:50', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:55', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'None (0)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:37:59', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered 'No (N)'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-05T23:38:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '87487c84-4ac2-4ef8-a94a-49995925c77d' User entered '05 Sep 2020 23:38'	System	06 Sep 2020 05:38:05
	System	06 Sep 2020 05:38:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 3'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:29', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:32', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:36', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:39', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:42', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:44', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'None (0)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:51', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered 'No (N)'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-06T15:29:54', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'e69f65e0-0aa6-42b6-9b48-d7c164434713' User entered '06 Sep 2020 15:29'	System	06 Sep 2020 21:29:58
	System	06 Sep 2020 21:29:58

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 4'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:35', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:37', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:43', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:48', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'None (0)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered 'No (N)'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-07T14:45:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c50e0bfe-9e1f-4bee-b27e-0ced1aa0698f' User entered '07 Sep 2020 14:45'	System	07 Sep 2020 20:45:59
	System	07 Sep 2020 20:45:59

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 5'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:44', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:47', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:51', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:54', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:51:57', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'None (0)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:52:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered 'No (N)'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-08T19:52:06', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'bac8c676-c1d6-47c3-87ac-2f9a84113ec8' User entered '08 Sep 2020 19:52'	System	09 Sep 2020 22:19:05
	System	09 Sep 2020 22:19:05

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 6'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:49', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:55', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:19:57', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:20:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:20:02', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'None (0)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:20:05', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered 'No (N)'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-09T16:20:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '237dc25a-f29d-4388-80f0-77abf1cbbe8d' User entered '09 Sep 2020 16:20'	System	09 Sep 2020 22:20:10
	System	09 Sep 2020 22:20:10

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 7'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:55:18

US3142268

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:45:09
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 23:26:40

US3142268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:45:09
User entered '11 Sep 2020'	Jill York (b) (4)	30 Sep 2020 23:26:40

US3142268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:45:09
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	30 Sep 2020 23:26:40

US3142268

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:45:09
User entered empty.	Jill York (b) (4)	30 Sep 2020 23:26:40

US3142268

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:39:16
DataPoint Un-verified.		11 Nov 2020 20:45:40
DataPoint Verified.		11 Nov 2020 20:45:37
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	30 Sep 2020 22:30:28
	(b) (4)	

US3142268

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'I'	System	30 Sep 2020 22:30:28

US3142268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:11
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 23:27:01

US3142268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:14
User entered '18 Sep 2020'	Jill York (b) (4)	30 Sep 2020 23:27:01

US3142268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:14
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	30 Sep 2020 23:27:01

US3142268

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:46:14
User entered empty.	Jill York (b) (4)	30 Sep 2020 23:27:01

US3142268

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:40:01
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	30 Sep 2020 22:30:33
	(b) (4)	

US3142268

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'I'	System	30 Sep 2020 22:30:33

US3142268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:18
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 23:27:18

US3142268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:18
User entered '28 Sep 2020'	Jill York (b) (4)	30 Sep 2020 23:27:18

US3142268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:18
User entered 'Contact Made (CONTACT MADE)'	Jill York (b) (4)	30 Sep 2020 23:27:18

US3142268

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:18
User entered empty.	Jill York (b) (4)	30 Sep 2020 23:27:18

US3142268

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:47:26
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	30 Sep 2020 22:30:39
	(b) (4)	

US3142268

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User entered 'I'	System	30 Sep 2020 22:30:39

US3142268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:31
DataPoint Un-verified.		11 Nov 2020 20:48:44
DataPoint Verified.		11 Nov 2020 20:48:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).		04 Nov 2020 07:29:56
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'now completed ' (Site from DM).	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:40:29
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:01:44
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 22:40:50

US3142268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:14
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 22:40:50

US3142268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:48:14
User entered 'Clinic (Clinic)'	Jill York (b) (4)	30 Sep 2020 22:40:50

US3142268

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'VISIT2'	System	30 Sep 2020 22:40:50

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User accepted default value 'Pre-Dose (PREDOSE)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '15:57'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '30 Sep 2020 15:57'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '97.5' F	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'Other (Other)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'temporal'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '87'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'bpm'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '15'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'breaths/min'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '148'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '90'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User accepted default value 'Post-Dose (POSTDOSE)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '16:50'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '30 Sep 2020 16:50'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '97.8' F	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'Other (Other)'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered 'temporal'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '85'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'bpm'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '14'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'breaths/min'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '149'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:49:55
User entered '92'	Jill York (b) (4)	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	30 Sep 2020 23:30:37

US3142268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:15
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 22:40:59

US3142268

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:16
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 22:40:59

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered empty.	Shelby Pickle (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered '30 Sep 2020'	Shelby Pickle (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered '16:20'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '30 Sep 2020 16:20'	System	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:50:44
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4) (b) (4)	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
DataPoint Verified.		11 Nov 2020 20:50:44
User entered 'ONCE'	System	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:21:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 22:31:03

US3142268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:41:01
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 22:41:41

US3142268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:41:01
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 22:41:41

US3142268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:41:01
User entered '16:17'	Jill York (b) (4)	30 Sep 2020 22:41:41

US3142268

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '30 Sep 2020 16:17'	System	30 Sep 2020 22:41:41

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:21:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:41:14
User entered '30 Sep 2020'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:41:14
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:41:14
User entered '16:10'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '30 Sep 2020 16:10'	System	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:41:14
User entered 'No (N)'	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:41:14
User entered empty.	Jill York (b) (4)	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered empty.	System	30 Sep 2020 22:41:58

US3142268

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:40:27
User entered 'Yes (Y)'	Jill York (b) (4)	30 Sep 2020 22:41:06

US3142268

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	30 Sep 2020 22:41:06

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:13', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '226794c3-0bf6-4364-8f3b-787bf2cc10ff' User entered 'Yes (Y)'	System	30 Sep 2020 22:53:19
	System	30 Sep 2020 22:53:19

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '226794c3-0bf6-4364-8f3b-787bf2cc10ff' User entered '97.8'	System	30 Sep 2020 22:53:19
	System	30 Sep 2020 22:53:19

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:07', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '226794c3-0bf6-4364-8f3b-787bf2cc10ff' User entered 'No (N)'	System	30 Sep 2020 22:53:19
	System	30 Sep 2020 22:53:19

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:18', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '226794c3-0bf6-4364-8f3b-787bf2cc10ff' User entered '30 Sep 2020 16:53'	System	30 Sep 2020 22:53:19
	System	30 Sep 2020 22:53:19

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 16:40'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 19:10'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:05', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2b709e2f-8dc8-4daa-9ef6-2fa54b29a01e' User entered 'Yes (Y)'	System	01 Oct 2020 12:31:23
	System	01 Oct 2020 12:31:23

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:11', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2b709e2f-8dc8-4daa-9ef6-2fa54b29a01e' User entered '97.6'	System	01 Oct 2020 12:31:23
	System	01 Oct 2020 12:31:23

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2b709e2f-8dc8-4daa-9ef6-2fa54b29a01e'	System	01 Oct 2020 12:31:23
User entered 'No (N)'	System	01 Oct 2020 12:31:23

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2b709e2f-8dc8-4daa-9ef6-2fa54b29a01e' User entered '01 Oct 2020 06:31'	System	01 Oct 2020 12:31:23
	System	01 Oct 2020 12:31:23

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 2'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:15:47', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'dc7f09f7-5818-4d11-8f59-130c90ed78e9' User entered 'Yes (Y)'	System	02 Oct 2020 00:16:07
	System	02 Oct 2020 00:16:07

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:15:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'dc7f09f7-5818-4d11-8f59-130c90ed78e9' User entered '98.2'	System	02 Oct 2020 00:16:07
	System	02 Oct 2020 00:16:07

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'dc7f09f7-5818-4d11-8f59-130c90ed78e9'	System	02 Oct 2020 00:16:07
User entered 'No (N)'	System	02 Oct 2020 00:16:07

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:04', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'dc7f09f7-5818-4d11-8f59-130c90ed78e9' User entered '01 Oct 2020 18:16'	System	02 Oct 2020 00:16:07
	System	02 Oct 2020 00:16:07

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 3'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:40:24', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0198c276-b1f3-4f37-9a26-62aba8386126' User entered 'Yes (Y)'	System	02 Oct 2020 20:40:45
	System	02 Oct 2020 20:40:45

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:40:32', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0198c276-b1f3-4f37-9a26-62aba8386126' User entered '99.7'	System	02 Oct 2020 20:40:45
	System	02 Oct 2020 20:40:45

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:40:37', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0198c276-b1f3-4f37-9a26-62aba8386126'	System	02 Oct 2020 20:40:45
User entered 'No (N)'	System	02 Oct 2020 20:40:45

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:40:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0198c276-b1f3-4f37-9a26-62aba8386126' User entered '02 Oct 2020 14:40'	System	02 Oct 2020 20:40:45
	System	02 Oct 2020 20:40:45

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 4'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:38:30', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257'	System	03 Oct 2020 20:39:05
User entered 'Yes (Y)'	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:38:39', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257' User entered '97.9'	System	03 Oct 2020 20:39:05
	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:38:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257'	System	03 Oct 2020 20:39:05
User entered 'Yes (Y)'	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. Medication is now listed under ConMed page. ' (Site from System).	(b) (4)	17 Nov 2020 02:31:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Meghan York (b) (4)	13 Nov 2020 16:59:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:38:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257'	(b) (4)	
User entered '1'	System	03 Oct 2020 20:39:05
	System	03 Oct 2020 20:39:05
	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:38:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257'	System	03 Oct 2020 20:39:05
User entered '0'	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '584ed853-621a-4bf9-8397-02fa1d0fe257'	System	03 Oct 2020 20:39:05
User entered '03 Oct 2020 15:39'	System	03 Oct 2020 20:39:05

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 5'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '89fdd70b-344d-45c2-9669-febbbc260cb0' User entered 'Yes (Y)'	System	04 Oct 2020 23:31:18
	System	04 Oct 2020 23:31:18

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:09', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '89fdd70b-344d-45c2-9669-fefbbc260cb0' User entered '97.4'	System	04 Oct 2020 23:31:18
	System	04 Oct 2020 23:31:18

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:12', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '89fdd70b-344d-45c2-9669-febbbc260cb0' User entered 'No (N)'	System	04 Oct 2020 23:31:18
	System	04 Oct 2020 23:31:18

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:15', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '89fdd70b-344d-45c2-9669-fefbbc260cb0' User entered '04 Oct 2020 18:31'	System	04 Oct 2020 23:31:18
	System	04 Oct 2020 23:31:18

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 6'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:19', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f3ae0d06-e156-4f31-96b5-1edd0cc209ec' User entered 'Yes (Y)'	System	05 Oct 2020 19:18:38
	System	05 Oct 2020 19:18:38

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:27', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f3ae0d06-e156-4f31-96b5-1edd0cc209ec' User entered '97.4'	System	05 Oct 2020 19:18:38
	System	05 Oct 2020 19:18:38

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:31', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f3ae0d06-e156-4f31-96b5-1edd0cc209ec' User entered 'No (N)'	System	05 Oct 2020 19:18:38
	System	05 Oct 2020 19:18:38

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:35', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f3ae0d06-e156-4f31-96b5-1edd0cc209ec' User entered '05 Oct 2020 14:18'	System	05 Oct 2020 19:18:38
	System	05 Oct 2020 19:18:38

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 7'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:30', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f069966c-c117-453b-9010-3b73107b884d'	System	30 Sep 2020 22:53:58
User entered 'None (1)'	System	30 Sep 2020 22:53:58

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:37', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f069966c-c117-453b-9010-3b73107b884d' User entered 'No (N)'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:43', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f069966c-c117-453b-9010-3b73107b884d' User entered 'No (N)'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:50', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f069966c-c117-453b-9010-3b73107b884d' User entered 'None (1)'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:54', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'f069966c-c117-453b-9010-3b73107b884d' User entered '30 Sep 2020 16:53'	System	30 Sep 2020 22:53:58
	System	30 Sep 2020 22:53:58

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 16:40'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 19:10'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:25', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2ca22767-1f48-4cf2-939e-e7ebd49e1f0b' User entered 'None (1)'	System	01 Oct 2020 12:31:46
	System	01 Oct 2020 12:31:46

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:28', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2ca22767-1f48-4cf2-939e-e7ebd49e1f0b' User entered 'No (N)'	System	01 Oct 2020 12:31:46
	System	01 Oct 2020 12:31:46

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:32', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2ca22767-1f48-4cf2-939e-e7ebd49e1f0b' User entered 'No (N)'	System	01 Oct 2020 12:31:46
	System	01 Oct 2020 12:31:46

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:39', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2ca22767-1f48-4cf2-939e-e7ebd49e1f0b' User entered 'None (1)'	System	01 Oct 2020 12:31:46
	System	01 Oct 2020 12:31:46

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:42', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '2ca22767-1f48-4cf2-939e-e7ebd49e1f0b' User entered '01 Oct 2020 06:31'	System	01 Oct 2020 12:31:46
	System	01 Oct 2020 12:31:46

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 2'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '841830da-a994-4b33-91d0-d240fe1341e2'	System	02 Oct 2020 00:17:06
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 00:17:06

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:27', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '841830da-a994-4b33-91d0-d240fe1341e2' User entered 'No (N)'	System	02 Oct 2020 00:17:06
	System	02 Oct 2020 00:17:06

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:46', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '841830da-a994-4b33-91d0-d240fe1341e2' User entered 'No (N)'	System	02 Oct 2020 00:17:06
	System	02 Oct 2020 00:17:06

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:16:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '841830da-a994-4b33-91d0-d240fe1341e2'	System	02 Oct 2020 00:17:06
User entered 'None (1)'	System	02 Oct 2020 00:17:06

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '841830da-a994-4b33-91d0-d240fe1341e2' User entered '01 Oct 2020 18:17'	System	02 Oct 2020 00:17:06
	System	02 Oct 2020 00:17:06

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 3'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'cfc79bbd-9528-421f-b74c-817366c984e8'	System	02 Oct 2020 20:41:42
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 20:41:42

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:23', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'cfc79bbd-9528-421f-b74c-817366c984e8' User entered 'No (N)'	System	02 Oct 2020 20:41:42
	System	02 Oct 2020 20:41:42

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:33', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'cfc79bbd-9528-421f-b74c-817366c984e8' User entered 'No (N)'	System	02 Oct 2020 20:41:42
	System	02 Oct 2020 20:41:42

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:37', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'cfc79bbd-9528-421f-b74c-817366c984e8'	System	02 Oct 2020 20:41:42
User entered 'None (1)'	System	02 Oct 2020 20:41:42

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:40', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'cfc79bbd-9528-421f-b74c-817366c984e8' User entered '02 Oct 2020 14:41'	System	02 Oct 2020 20:41:42
	System	02 Oct 2020 20:41:42

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 4'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:05', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '36052a05-bd5f-4bfd-9843-522fc7854f99'	System	03 Oct 2020 20:39:26
User entered 'None (1)'	System	03 Oct 2020 20:39:26

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '36052a05-bd5f-4bfd-9843-522fc7854f99'	System	03 Oct 2020 20:39:26
User entered 'No (N)'	System	03 Oct 2020 20:39:26

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:11', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '36052a05-bd5f-4bfd-9843-522fc7854f99'	System	03 Oct 2020 20:39:26
User entered 'No (N)'	System	03 Oct 2020 20:39:26

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:15', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '36052a05-bd5f-4bfd-9843-522fc7854f99'	System	03 Oct 2020 20:39:26
User entered 'None (1)'	System	03 Oct 2020 20:39:26

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:18', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '36052a05-bd5f-4bfd-9843-522fc7854f99' User entered '03 Oct 2020 15:39'	System	03 Oct 2020 20:39:26
	System	03 Oct 2020 20:39:26

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 5'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '08c88fdc-3a55-4845-936b-a30dd3f7848a'	System	04 Oct 2020 23:31:34
User entered 'None (1)'	System	04 Oct 2020 23:31:34

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:23', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '08c88fdc-3a55-4845-936b-a30dd3f7848a' User entered 'No (N)'	System	04 Oct 2020 23:31:34
	System	04 Oct 2020 23:31:34

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:25', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '08c88fdc-3a55-4845-936b-a30dd3f7848a' User entered 'No (N)'	System	04 Oct 2020 23:31:34
	System	04 Oct 2020 23:31:34

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:29', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '08c88fdc-3a55-4845-936b-a30dd3f7848a' User entered 'None (1)'	System	04 Oct 2020 23:31:34
	System	04 Oct 2020 23:31:34

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:31', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '08c88fdc-3a55-4845-936b-a30dd3f7848a' User entered '04 Oct 2020 18:31'	System	04 Oct 2020 23:31:34
	System	04 Oct 2020 23:31:34

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 6'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:40', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '9e0ad811-2aef-41f4-ac15-ef970aedfd8f' User entered 'None (1)'	System	05 Oct 2020 19:18:56
	System	05 Oct 2020 19:18:56

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:43', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '9e0ad811-2aef-41f4-ac15-ef970aedfd8f' User entered 'No (N)'	System	05 Oct 2020 19:18:56
	System	05 Oct 2020 19:18:56

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:46', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '9e0ad811-2aef-41f4-ac15-ef970aedfd8f' User entered 'No (N)'	System	05 Oct 2020 19:18:56
	System	05 Oct 2020 19:18:56

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:50', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '9e0ad811-2aef-41f4-ac15-ef970aedfd8f' User entered 'None (1)'	System	05 Oct 2020 19:18:56
	System	05 Oct 2020 19:18:56

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '9e0ad811-2aef-41f4-ac15-ef970aedfd8f' User entered '05 Oct 2020 14:18'	System	05 Oct 2020 19:18:56
	System	05 Oct 2020 19:18:56

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 7'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:53:59', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:02', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:05', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:10', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:13', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered 'None (0)'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:18', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0'	System	30 Sep 2020 22:54:23
User entered 'No (N)'	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-09-30T16:54:20', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '610c3f5f-200c-441f-a1f4-2d481d7b9bd0' User entered '30 Sep 2020 16:54'	System	30 Sep 2020 22:54:23
	System	30 Sep 2020 22:54:23

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 16:40'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 19:10'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:48', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:51', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:54', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:31:57', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:32:01', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:32:04', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered 'None (0)'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:32:09', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2'	System	01 Oct 2020 12:32:14
User entered 'No (N)'	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T06:32:12', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'a83f413d-fa60-454b-b8c7-8933f1cf6ad2' User entered '01 Oct 2020 06:32'	System	01 Oct 2020 12:32:14
	System	01 Oct 2020 12:32:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '30 Sep 2020 20:05'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 2'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:04', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:07', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:10', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:13', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:18', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'None (0)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:22', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered 'No (N)'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-01T18:17:24', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '80e824ea-6911-4117-987e-b2f68a9fa571' User entered '01 Oct 2020 18:17'	System	02 Oct 2020 00:17:27
	System	02 Oct 2020 00:17:27

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 3'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:41:57', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13'	System	02 Oct 2020 20:42:46
User entered 'No interference with activity (1)'	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:10', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13'	System	02 Oct 2020 20:42:46
User entered 'No interference with activity (1)'	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:15', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13' User entered 'None (0)'	System	02 Oct 2020 20:42:46
	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:18', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13' User entered 'None (0)'	System	02 Oct 2020 20:42:46
	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:26', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13'	System	02 Oct 2020 20:42:46
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:30', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13'	System	02 Oct 2020 20:42:46
User entered 'No interference with activity (1)'	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:35', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13' User entered 'No (N)'	System	02 Oct 2020 20:42:46
	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-02T14:42:38', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '0a98d301-07b3-44bf-8e64-46ca9be91e13' User entered '02 Oct 2020 14:42'	System	02 Oct 2020 20:42:46
	System	02 Oct 2020 20:42:46

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 4'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:36', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b'	System	03 Oct 2020 20:40:07
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:41', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b' User entered 'None (0)'	System	03 Oct 2020 20:40:07
	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:44', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b' User entered 'None (0)'	System	03 Oct 2020 20:40:07
	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:47', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b' User entered 'None (0)'	System	03 Oct 2020 20:40:07
	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:52', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b'	System	03 Oct 2020 20:40:07
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:39:56', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b'	System	03 Oct 2020 20:40:07
User entered 'No interference with activity (1)'	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:40:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b' User entered 'No (N)'	System	03 Oct 2020 20:40:07
	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-03T15:40:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'd566b410-b183-46d4-9a1b-eeac8ce8167b' User entered '03 Oct 2020 15:40'	System	03 Oct 2020 20:40:07
	System	03 Oct 2020 20:40:07

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 5'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:35', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:38', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:40', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:43', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:45', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:48', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'None (0)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:51', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered 'No (N)'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-04T18:31:55', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '089e56d1-4452-4212-ae5b-68378cec0e80' User entered '04 Oct 2020 18:31'	System	04 Oct 2020 23:31:57
	System	04 Oct 2020 23:31:57

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 6'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:18:57', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:03', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:05', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:08', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:11', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'None (0)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:14', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered 'No (N)'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07F31D5A-C6A3-4BF3-811B-D1338ACD966A)', Time: '2020-10-05T14:19:16', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '1ebee56b-8c5e-47ff-a12a-d0dea554dccf' User entered '05 Oct 2020 14:19'	System	05 Oct 2020 19:19:20
	System	05 Oct 2020 19:19:20

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
Data entry locked.	System	30 Sep 2020 22:31:03
User entered 'Day 7'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 22:31:03

US3142268

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:05:14
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 22:31:03

US3142268

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Oct 2020 22:56:44

US3142268

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered '9 Oct 2020'	Jami Wagner (b) (4)	12 Oct 2020 22:56:44

US3142268

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	12 Oct 2020 22:56:44

US3142268

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:54:41
User entered empty.	Jami Wagner (b) (4) (b) (4)	12 Oct 2020 22:56:44

US3142268

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:56
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Oct 2020 22:56:49

US3142268

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	12 Oct 2020 22:56:49

US3142268

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:55:36
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	20 Oct 2020 19:36:46

US3142268

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:55:36
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		28 Oct 2020 14:56:20
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:04:33
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	20 Oct 2020 19:36:46
User entered '19 Oct 2020'	Dalia Jeronimo (b) (4) (b) (4)	20 Oct 2020 19:36:46

US3142268

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:55:36
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	20 Oct 2020 19:36:46

US3142268

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:55:36
User entered empty.	Dalia Jeronimo (b) (4)	20 Oct 2020 19:36:46

US3142268

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:44:47
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	20 Oct 2020 19:36:53

US3142268

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	20 Oct 2020 19:36:53

US3142268

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:25
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	23 Oct 2020 19:37:14

US3142268

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:25
User entered '23 Oct 2020'	Dalia Jeronimo (b) (4)	23 Oct 2020 19:37:14

US3142268

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:25
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	23 Oct 2020 19:37:14

US3142268

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:25
User entered empty.	Dalia Jeronimo (b) (4) (b) (4)	23 Oct 2020 19:37:14

US3142268

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:45:08
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	23 Oct 2020 19:36:46

US3142268

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	23 Oct 2020 19:36:46

US3142268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
User closed query 'Please verify if nausea 13Oct2020 should be added as an AE. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 17:26:19
Query 'Please verify if nausea 13Oct2020 should be added as an AE. ' answered with 'nausea has been entered as an adverse event ' (Site from CRA).	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:49:23
User opened query 'Please verify if nausea 13Oct2020 should be added as an AE. ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 16:46:06
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:40:47

US3142268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:46:06
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		10 Nov 2020 03:44:47
User entered '16 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	09 Nov 2020 19:56:50
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'information is correct ' (Site from System).	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:40:58
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	03 Nov 2020 22:40:47
User entered '7 Oct 2020'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:40:47

US3142268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:46:06
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:40:47

US3142268

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'VISIT3'	System	03 Nov 2020 22:40:47

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:22
User entered 'Yes (Y)'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:29
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:56:50
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Nov 2020 19:56:50
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:56:30
User entered '16 Oct 2020'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:31
User entered '15:00'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '16 Oct 2020 15:00'	System	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:35
User entered '97.8' F	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:53:37
User entered 'Other (Other)'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:40
User entered 'temporal'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:44
User entered '80'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'bpm'	System	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:51
User entered '17'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'breaths/min'	System	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:53
User entered '155'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:53:55
User entered '92'	Jill York (b) (4)	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'mmHg'	System	09 Nov 2020 19:56:30

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37

US3142268

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37

US3142268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User closed query 'thank you for adding to eCRF page, Please add Phenergan 25 mg to the conmed list in source documentation.' (Site from CRA).		21 Apr 2021 01:25:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
Query 'thank you for adding to eCRF page, Please add Phenergan 25 mg to the conmed list in source documentation.' answered with 'data now entered ' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 16:12:51
User closed query 'Please verify if nausea dated 13Oct2020 as per progress note should be entered as an AE.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 16:52:17
User opened query 'thank you for adding to eCRF page, Please add Phenergan 25 mg to the conmed list in source documentation.' (Site from CRA).		17 Dec 2020 16:49:12
User closed query 'Please verify if Phenergan 25 mg should be added to the con meds as per 16Oct 2020 progress notes' (Site from CRA).		17 Dec 2020 16:49:12
Query 'Please verify if nausea dated 13Oct2020 as per progress note should be entered as an AE.' answered with 'not considred an AE' (Site from CRA).	Meghan York (b) (4)	17 Nov 2020 21:59:35
Query 'Please verify if Phenergan 25 mg should be added to the con meds as per 16Oct 2020 progress notes' answered with 'added to conmed list' (Site from CRA).	Meghan York (b) (4)	17 Nov 2020 21:59:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:54:14
User opened query 'Please verify if Phenergan 25 mg should be added to the con meds as per 16Oct 2020 progress notes' (Site from CRA).		11 Nov 2020 21:52:13
User opened query 'Please verify if nausea dated 13Oct2020 as per progress note should be entered as an AE.' (Site from CRA).		11 Nov 2020 21:49:41
User entered 'Yes (Y)'	Meghan York (b) (4)	03 Nov 2020 22:41:09

US3142268

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:54:21
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:57:16
User entered '16 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	09 Nov 2020 19:57:16
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:56:50
User entered '7 Oct 2020'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:41:09

US3142268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User closed query 'Please enter source documents for this visit.' (Site from CRA).		17 Dec 2020 16:50:08
Query 'Please enter source documents for this visit.' answered with 'source is filed ' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:47:36
User opened query 'Please enter source documents for this visit.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:55:44
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:41:23

US3142268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:58:03
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		09 Nov 2020 19:58:03
User entered '16 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	09 Nov 2020 19:58:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Nov 2020 19:56:50
User entered '7 Oct 2020'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:41:23

US3142268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:50:35
User entered '14:50' reason for change: Data Entry Error	Jill York (b) (4)	09 Nov 2020 19:57:38
User entered '11:28'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:41:23

US3142268

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered '16 Oct 2020 14:50'	System	09 Nov 2020 19:58:03
User entered '7 Oct 2020 14:50'	System	09 Nov 2020 19:57:38
User entered '7 Oct 2020 11:28'	System	03 Nov 2020 22:41:23

US3142268

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:55:55
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:41:28

US3142268

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	03 Nov 2020 22:41:28

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 64'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:21:56

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 71'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 22:55:18

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 22:55:18

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered 'Day 78'	System	04 Sep 2020 22:55:18

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Folder: Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

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Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
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[Chills](#)

Audit	User	Time (GMT)
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US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 22:55:18

US3142268

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:12:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:38:20
Data entry locked.	System	04 Sep 2020 22:55:18
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 22:55:18

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:38:20

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C413C21-F7A9-4875-94A6-65E8EA9496C8)', Time: '2021-05-03T13:36:42-06:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '336e357c-3832-42e9-91db-51e7884f9416'	System	03 May 2021 19:37:09
User entered 'No (N)'	System	03 May 2021 19:37:09

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C413C21-F7A9-4875-94A6-65E8EA9496C8)', Time: '2021-05-03T13:36:51-06:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '336e357c-3832-42e9-91db-51e7884f9416'	System	03 May 2021 19:37:09
User entered 'No (N)'	System	03 May 2021 19:37:09

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C413C21-F7A9-4875-94A6-65E8EA9496C8)', Time: '2021-05-03T13:36:55-06:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: '336e357c-3832-42e9-91db-51e7884f9416'	System	03 May 2021 19:37:09
User entered '03 May 2021 13:36:55'	System	03 May 2021 19:37:09

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 05:38:20

US3142268

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:38:20
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 05:38:20

US3142268

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:21:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:49:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C413C21-F7A9-4875-94A6-65E8EA9496C8)', Time: '2021-05-03T13:36:15-06:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c8505788-1d09-476f-9682-ffc5318afacc'	System	03 May 2021 19:36:23
User entered 'No (N)'	System	03 May 2021 19:36:23

US3142268

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:21:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:49:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9C413C21-F7A9-4875-94A6-65E8EA9496C8)', Time: '2021-05-03T13:36:19-06:00', User OID: 'PatientReportedOutcome (US3142268)', ODM File OID: 'c8505788-1d09-476f-9682-ffc5318afacc' User entered '03 May 2021 13:36:19'	System	03 May 2021 19:36:23
	System	03 May 2021 19:36:23

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:08:37
User entered 'Yes (Y)'	Jami Wagner (b) (4)	23 Nov 2020 18:35:56

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:08:38
User entered '23 Nov 2020'	Jami Wagner (b) (4)	23 Nov 2020 18:35:56

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:08:40
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	23 Nov 2020 18:35:56

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User closed query 'Please add Protanix to the source documents.' (Site from CRA).		21 Apr 2021 01:27:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
Query 'Please add Protanix to the source documents.' answered with 'done ' (Site from CRA).	(b) (4)	
User opened query 'Please add Protanix to the source documents.' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 16:14:40
User closed query 'Please add Protanix to Con Med source document as appropriate.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 23:54:40
Query 'Please add Protanix to Con Med source document as appropriate.' answered with 'done ' (Site from CRA).		01 Mar 2021 23:54:40
User opened query 'Please add Protanix to Con Med source document as appropriate.' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 20:00:17
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:14:23
User closed query 'Per DM CLR: Comment = SUBJECT IS NOW TAKING PROTANIX 40MG A DAY FOR AN ULCER. Review if this medication/vaccination should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate.' (Site from DM).		06 Jan 2021 19:12:52
Query 'Per DM CLR: Comment = SUBJECT IS NOW TAKING PROTANIX 40MG A DAY FOR AN ULCER. Review if this medication/vaccination should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate.' answered with 'now entered into the Conmed page ' (Site from DM).		24 Dec 2020 19:13:21
User opened query 'Per DM CLR: Comment = SUBJECT IS NOW TAKING PROTANIX 40MG A DAY FOR AN ULCER. Review if this medication/vaccination should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate.' (Site from DM).	Meghan York (b) (4)	17 Dec 2020 18:48:19
	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 09:08:43

US3142268

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'subject is now taking protanix 40mg a day for an ulcer'	Jami Wagner (b) (4) (b) (4)	23 Nov 2020 18:35:56

US3142268

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User closed query 'Please please provide SD and response to this page' (Site from CRA).	(b) (4)	12 Apr 2021 16:32:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:36
Query 'Please please provide SD and response to this page' answered with 'done ' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 16:15:17
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:53
User opened query 'Please please provide SD and response to this page' (Site from CRA).		01 Apr 2021 21:53:34
DataPoint Verified.		01 Apr 2021 21:49:37
User entered 'Yes (Y)'	Jami Wagner (b) (4)	23 Nov 2020 18:36:01
	(b) (4)	

US3142268

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:27:37
User entered 'I'	System	23 Nov 2020 18:36:01

US3142268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered 'No (N)'	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 18:00:05
	(b) (4)	

US3142268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 18:00:05
	(b) (4)	

US3142268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 18:00:05
	(b) (4)	

US3142268

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:47
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4) Lisa Jackson (b) (4) (b) (4)	12 Apr 2021 18:00:05

US3142268

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:10
DataPoint Un-verified.		01 Apr 2021 21:57:48
DataPoint Verified.		01 Apr 2021 21:50:09
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	18 Mar 2021 22:39:45
	(b) (4)	

US3142268

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User entered 'I'	System	18 Mar 2021 22:39:45

US3142268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:48:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered 'No (N)'	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:59:45
	(b) (4)	

US3142268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:48:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:59:45
	(b) (4)	

US3142268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:48:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:59:45
	(b) (4)	

US3142268

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:48:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:59:45
	(b) (4)	

US3142268

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'Please provide SD and complete visit page' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:50:58
Query 'Please provide SD and complete visit page' answered with 'done' (Site from CRA).	Jami Wagner (b) (4)	12 Apr 2021 21:29:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:33:07
User opened query 'Please provide SD and complete visit page' (Site from CRA).		01 Apr 2021 21:56:20
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	18 Mar 2021 22:39:57
	(b) (4)	

US3142268

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User entered 'I'	System	18 Mar 2021 22:39:57

US3142268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered 'No (N)'	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:57:09
	(b) (4)	

US3142268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:57:09
	(b) (4)	

US3142268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4)	
	Lisa Jackson (b) (4)	12 Apr 2021 17:57:09
	(b) (4)	

US3142268

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
DataPoint Verified.		19 Apr 2021 20:49:19
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User entered empty.	(b) (4) Lisa Jackson (b) (4) (b) (4)	12 Apr 2021 17:57:09

US3142268

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'Please provide SD and enter response on page' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:51:17
Query 'Please provide SD and enter response on page' answered with 'done' (Site from CRA).	Jami Wagner (b) (4)	12 Apr 2021 21:08:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:27
User opened query 'Please provide SD and enter response on page' (Site from CRA).		01 Apr 2021 21:55:14
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	18 Mar 2021 22:40:13
	(b) (4)	

US3142268

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:47:14
User entered 'I'	System	18 Mar 2021 22:40:13

US3142268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:48:51
User entered 'Yes (Y)'	Lisa Jackson (b) (4)	18 Mar 2021 22:40:40

US3142268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:48:51
User entered '18 Mar 2021'	Lisa Jackson (b) (4)	18 Mar 2021 22:40:40

US3142268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:48:51
User entered 'Clinic (Clinic)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 22:40:40

US3142268

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered 'VISIT4'	System	18 Mar 2021 22:40:40

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered 'No (N)'	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered empty.	System	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4) (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered empty.	System	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered empty.	System	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered empty.	System	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:27:01
User entered empty.	Lisa Jackson (b) (4)	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered empty.	System	12 Apr 2021 17:51:43

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41

US3142268

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41

US3142268

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:49:09
User entered 'No (N)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 22:40:48

US3142268

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:49:09
User entered empty.	Lisa Jackson (b) (4)	18 Mar 2021 22:40:48

US3142268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:49:16
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 22:41:18

US3142268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:49:16
User entered '18 Mar 2021'	Lisa Jackson (b) (4)	18 Mar 2021 22:41:18

US3142268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:49:16
User entered '16:21'	Lisa Jackson (b) (4)	18 Mar 2021 22:41:18

US3142268

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered '18 Mar 2021 16:21'	System	18 Mar 2021 22:41:18

US3142268

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:46:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:49:23
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	18 Mar 2021 22:41:24

US3142268

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:12:41
User entered '1'	System	18 Mar 2021 22:41:24

US3142268

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	03 May 2021 21:27:40

US3142268

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Apr 2021'	Lisa Jackson (b) (4) (b) (4)	03 May 2021 21:27:40

US3142268

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lisa Jackson (b) (4) (b) (4)	03 May 2021 21:27:40

US3142268

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lisa Jackson (b) (4) (b) (4)	03 May 2021 21:27:40

US3142268

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lisa Jackson (b) (4) (b) (4)	03 May 2021 21:27:49

US3142268

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 21:27:49

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:05:55
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:38:11

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:05:55
User entered '15 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:38:11

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:05:55
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4)	15 Jan 2021 16:38:11

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 16:38:11

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:01:31
User entered '15 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:26:23
User entered '0'	Jami Wagner (b) (4)	09 Apr 2021 19:31:58
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:45:00

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:01:31
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:19:23
		12 Apr 2021 22:26:25
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:32:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 19:31:58
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	09 Apr 2021 17:46:03
	System	06 Mar 2021 14:45:00

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:01:31
User entered '15 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:01:31
User entered 'mRNA-1273 (mRNA-1273)'	Jami Wagner (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:01:31
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:08:04
User entered 'mRNA-1273 (mRNA-1273)'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:01:31
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:08:04
User entered 'mRNA-1273 (mRNA-1273)'	Jami Wagner (b) (4) (b) (4)	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:01:31
User entered 'No (N)'	Jami Wagner (b) (4)	15 Jan 2021 16:39:02

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User entered empty.	System	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:21:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User entered empty.	System	15 Jan 2021 16:39:02

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:07
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:39:23

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:07
User entered '15 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:39:23

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:07
User entered '09:22'	Jami Wagner (b) (4)	15 Jan 2021 16:39:23

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User entered '15 Jan 2021 09:22'	System	15 Jan 2021 16:39:23

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:17
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Jan 2021 16:39:51

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:17
User entered '15 Jan 2021'	Jami Wagner (b) (4)	15 Jan 2021 16:39:51

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:02:17
User entered '09:23'	Jami Wagner (b) (4)	15 Jan 2021 16:39:51

US3142268

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:21:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:21:03
User entered '15 Jan 2021 09:23'	System	15 Jan 2021 16:39:51

US3142268

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:21:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:15:14
User entered 'Yes (Y)'	Jill York (b) (4)	23 Oct 2020 17:40:35

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4)	16 Feb 2021 16:47:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:54:51
User entered	System	26 Oct 2020 20:54:46
'USA-US064-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	26 Oct 2020 20:54:46
User entered 'New'		

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:47:47
User closed query 'PV Query: Please consider updating the event term to duodenal ulcer.' (Site from Safety).		04 Nov 2020 17:23:00
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 22:37:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 22:37:26
Query 'PV Query: Please consider updating the event term to duodenal ulcer.' answered with 'done' (Site from Safety).	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:37:16
Data point term sent to Coder	System	03 Nov 2020 22:36:32
Coding entries removed.	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:36:21
User entered 'DUODENAL ULCER' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	03 Nov 2020 22:36:21
User opened query 'PV Query: Please consider updating the event term to duodenal ulcer.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:40:35
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:25:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:25:35
Data point term sent to Coder	System	23 Oct 2020 17:43:54
User entered 'hospitalization for duodenal ulcer'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:47:49
User entered 'Yes (Y)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:47:50
User entered 'No (N)'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:47:53
User entered 'No (N)'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:47:57
User entered '22 Oct 2020'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:00
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:30:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 23:44:20
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:44:20
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:44:20
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 23:43:59
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:48:03
User entered 'Yes (Y)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4)	01 Apr 2021 21:31:00
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:42:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added' (Site from Safety).	Jill York (b) (4)	18 Mar 2021 23:44:38
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:43:59
User entered '01 Mar 2021' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:43:59
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:48:19
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 22:54:23
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:51:24
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'no end date yet' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:43:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:39:36
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:21
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

Severity

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:27
User closed query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).		23 Nov 2020 19:51:30
Query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' answered with 'grade 3 is correct' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:44:05
User opened query 'PV Query: As event resulted in hospitalization, please confirm severity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:41:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:29
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Oct 2020 17:43:41
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Oct 2020 17:43:01
User entered 'Yes (Y)'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:39
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:41
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		02 Nov 2020 02:20:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'data is present' (Site from System).	Jill York (b) (4)	23 Oct 2020 17:44:28
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		23 Oct 2020 17:43:41
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	23 Oct 2020 17:43:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		23 Oct 2020 17:43:41
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	23 Oct 2020 17:43:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Oct 2020 17:43:01
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:45
User entered '22 Oct 2020'	Jill York (b) (4)	23 Oct 2020 17:43:01

US3142268

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4)	01 Apr 2021 21:31:40
User closed query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:43:04
Query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' answered with 'date added' (Site from Safety).	Jill York (b) (4)	18 Mar 2021 23:44:56
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:43:59
User entered '23 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:43:59
User opened query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:30:22
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 20:30:08
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:48:47
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 22:54:10
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:51:49
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'unknown at this time as site does not have medical records' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:44:36
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:39:22
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:19
User entered 'No (N)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:21
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:24
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:27
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:29
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:33
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:34
User entered 'Not Related (NOT RELATED)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:38
User closed query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		23 Nov 2020 19:51:59
Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.'	Jill York (b) (4)	20 Nov 2020 20:47:09
answered with 'corrected' (Site from Safety).		
User entered 'Not Applicable (NOT APPLICABLE)'	Jill York (b) (4)	20 Nov 2020 20:45:11
reason for change: Data Entry Error		
User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:39:11
User entered 'None (NONE)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:50:11
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:43:50
DataPoint Un-verified.	Jill York (b) (4)	22 Feb 2021 19:54:54
User entered '1' reason for change: Data Entry Error	Jill York (b) (4)	22 Feb 2021 19:54:54
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:50:13
User entered '0'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 03:04:22
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'con procedures added' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:36:54
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:50:15
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:13:48
User entered 'I'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:21:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:20:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'outcome is resolved per data entry' (Site from Safety).	Jill York (b) (4)	21 Apr 2021 14:35:58
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:32:34
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:43:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jill York (b) (4)	18 Mar 2021 23:43:59
Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 16:50:19
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 22:54:39
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:06
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:45:27
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not recovered' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:39:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 21:32:29
User entered empty.	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of CT abdomen/Pelvis from 23 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:57:27
Query 'PV Query: Please provide results of CT abdomen/Pelvis from 23 Oct 2020.' answered with 'negative' (Site from Safety).	Jill York (b) (4)	29 Apr 2021 23:22:17
User opened query 'PV Query: Please provide results of CT abdomen/Pelvis from 23 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:40:55
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:10:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		22 Apr 2021 11:20:03
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		22 Apr 2021 11:19:55
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		22 Apr 2021 11:17:04
User closed query 'Per DM CLR: Narrative indicates that the subject had Endoscopy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		22 Apr 2021 03:09:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User		Time (GMT)
User entered 'SUBJECT HOSPITALIZED DUE TO WORSENING NAUSEA. SUBJECT HAD ENDOSCOPY DONE 23 OCTOBER 2020 WHICH REVEALED A DUODENAL ULCER. SUBJECT HAD NEGATIVE COVID TEST 23OCT2020. SUBJECT GIVEN 3 UNITS OF PRBC DURING THE COURSE OF HOSPITALIZATION. SUBJECT'S HEMOGLOBIN DROPPED FROM 13.9 G/DL TO 8.2 G/DL DURING THE COURSE OF HOSPITALIZATION. SUBJECT HAD CT ABDOMEN/PELVIS AND AN EGD AND COLONOSCOPY 23OCT2020. EGD FINDINGS WERE SIGNIFICANT FOR 2 CM ULCER IN THE DUODENAL BULB WITH CLOT PRESENT.'	Jill York	(b) (4)	21 Apr 2021 16:26:21
reason for change: Data Entry Error Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'added to narrative' (Site from Safety).	Jill York	(b) (4)	21 Apr 2021 16:25:50
User entered 'SUBJECT HOSPITALIZED DUE TO WORSENING NAUSEA. SUBJECT HAD ENDOSCOPY DONE 23 OCTOBER 2020 WHICH REVEALED A DUODENAL ULCER. SUBJECT HAD NEGATIVE COVID TES 23OCT2020. SUBJECT GIVEN 3 UNITS OF PRBC DURING THE COURSE OF HOSPITALIZATION. SUBJECT'S HEMOGLOBIN DROPPED FROM 13.9 G/DL TO 8.2 G/DL DURING THE COURSE OF HOSPITALIZATION. SUBJECT HAD CT ABDOMEN/PELVIS AND AN EGD AND COLONOSCOPY 23OCT2020. EGD FINDINGS WERE SIGNIFICANT FOR 2 CM ULCER IN THE DUODENAL BULB With CLOT PRESENT.'	Jill York	(b) (4)	21 Apr 2021 16:25:30
reason for change: Data Entry Error DataPoint Un-verified.	Jill York	(b) (4)	21 Apr 2021 16:25:12

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User		Time (GMT)
User entered 'SUBJECT HOSPITALIZED DUE TO WORSENING NAUSEA. SUBJECT HAD ENDOSCOPY DONE 23 OCTOBER 2020 WHICH REVEALED A DUODENAL ULCER. Subject had negative COVID tes 23OCT2020. Subject given 3 units of PRBC during the course of hospitalization. Subject's hemoglobin dropped from 13.9 g/dL to 8.2 g/dL during the course of hospitalization. Subject had CT abdomen/pelvis and an EGD and colonoscopy 23OCT2020. EGD findings were significant for 2 cm ulcer in the duodenal bulb wiht clot present.' reason for change: Data Entry Error	Jill York	(b) (4)	21 Apr 2021 16:25:12
Query 'Per DM CLR: Narrative indicates that the subject had Endoscopy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.'	Jill York	(b) (4)	21 Apr 2021 15:43:31
answered with 'endoscopy added' (Site from DM). Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.'	Jill York	(b) (4)	21 Apr 2021 15:39:27
answered with 'no COVID testing done' (Site from Safety). Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.'	Jill York	(b) (4)	21 Apr 2021 14:36:20
answered with 'no pre-disposing risk factors' (Site from Safety). DataPoint Verified.		(b) (4), (b) (6)	12 Apr 2021 16:38:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.'			01 Mar 2021 20:31:06
canceled (Site from Safety).			

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had Endoscopy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 00:22:30
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		30 Nov 2020 22:55:45
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		30 Nov 2020 22:55:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Nov 2020 22:55:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Nov 2020 22:54:55
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		23 Nov 2020 19:52:51
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		23 Nov 2020 19:52:40
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 19:52:32

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:52:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'unknown at this time - site does not have medical records yet' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:46:55
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'unknown at this time - site does not have medical records yet' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:46:50
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'unknown' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:46:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'unknown at this time - site does not have medical records yet' (Site from Safety).	Jill York (b) (4)	20 Nov 2020 20:46:07
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:40:47
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:40:27

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:40:15
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		02 Nov 2020 14:40:06
User entered 'subject hospitalized due to worsening nausea. subject had endoscopy done 23 October 2020 which revealed a duodenal ulcer.'	Jill York (b) (4)	23 Oct 2020 17:43:01

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 17:43:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 22:46:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 22:46:53
Data point term sent to Coder	System	02 Dec 2020 22:46:07
User entered 'Nausea'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'No (N)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'No (N)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'No (N)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:24
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 15:36:20
User entered '02 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:36:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '13 Oct 2020'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User entered empty.	System	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'No (N)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'Per source, there is not stop date. Please follow-up with subject regarding AE/SAE and complete source documentation.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:10:20 23 Apr 2021 15:10:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 18:00:33
User entered '1 Nov 2020' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 18:00:33
Query 'Per source, there is not stop date. Please follow-up with subject regarding AE/SAE and complete source documentation.' answered with 'stop date is documented at D209 progress note and AE form' (Site from CRA).	Jill York (b) (4)	21 Apr 2021 15:42:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 15:41:58
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 15:41:58
User entered 'un Nov 2020' (non-conformant). DataPoint Verified.	Jill York (b) (4) (b) (4), (b) (6)	21 Apr 2021 15:41:58 12 Apr 2021 16:38:43
User opened query 'Per source, there is not stop date. Please follow-up with subject regarding AE/SAE and complete source documentation.' (Site from CRA).		19 Jan 2021 16:42:42
User entered '13 Oct 2020'	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User entered empty.	System	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered 'No (N)'	Meghan York (b) (4)	02 Dec 2020 22:45:20

US3142268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

US3142268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

US3142268

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:43
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 22:45:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:32
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:20
User entered empty.	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:43
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 22:45:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:32
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:20
User entered empty.	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:43
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 22:45:39
User entered 'None (NONE)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:39
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:20
User entered empty.	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0' reason for change: Data Entry Error	Meghan York (b) (4)	25 Jan 2021 19:09:38
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Dec 2020 22:45:47
User entered '1' reason for change: Data Entry Error	Meghan York (b) (4)	02 Dec 2020 22:45:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Dec 2020 22:45:20
User entered '0'	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 03:09:58
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'site to add conmed from hospitalization' (Site from DM).	Jill York (b) (4)	21 Apr 2021 15:43:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		29 Jan 2021 00:24:18
User entered '1' reason for change: Data Entry Error	Meghan York (b) (4)	25 Jan 2021 19:09:38
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered '0'	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:43
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:46:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 22:46:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:46:00
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:45:20
User entered empty.	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:38:43
User entered empty.	Meghan York (b) (4)	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User entered '0'	System	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38
User entered '0'	System	02 Dec 2020 22:45:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:16:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:21:56

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
User closed query 'Please follow-up on medical records.' (Site from CRA).	(b) (4)	12 Apr 2021 16:37:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:36:06
Query 'Please follow-up on medical records.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 16:17:15
User closed query 'Please enter procedure for "scope" (or endoscopy) as noted in progress note in Concomitant Procedures if you agree.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:20:38
User opened query 'Please follow-up on medical records.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:20:22
User closed query 'Per ETRTR: Pleas update Concomitant procedures as described for SAE "Duodenal Ulcer" page, thanks.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:20:22
User closed query 'Please enter con med as per source progress notes of 02Nov if appropriate,' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:22:58
Query 'Please enter con med as per source progress notes of 02Nov if appropriate,' answered with 'done' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:49:41
Query 'Per ETRTR: Pleas update Concomitant procedures as described for SAE "Duodenal Ulcer" page, thanks.' answered with 'unknown at this time - site does not have medical records yet' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:48:33
Query 'Please enter procedure for "scope" (or endoscopy) as noted in progress note in Concomitant Procedures if you agree.' answered with 'unknown at this time - site does not have medical records yet' (Site from CRA).	Jill York (b) (4)	20 Nov 2020 20:48:27
Query 'Please enter con meds as listed in the patient questionnaire if you agree' canceled (Site from CRA)	(b) (4), (b) (6)	11 Nov 2020 21:27:38
User opened query 'Please enter procedure for "scope" (or endoscopy) as noted in progress note in Concomitant Procedures if you agree.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:24:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:21:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Please enter con med as per source progress notes of 02Nov if appropriate,' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:12:41
User opened query 'Please enter con meds as listed in the patient questionnaire if you agree' (Site from CRA).		11 Nov 2020 20:31:37
User opened query 'Per ETRTR: Pleas update Concomitant procedures as described for SAE "Duodenal Ulcer" page, thanks.' (Site from CRA).		29 Oct 2020 19:45:35
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:40:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:42:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:42:45
Data point term sent to Coder	System	15 Sep 2020 19:41:33
User entered 'Zyrtec'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'seasonal allergies'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '10'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 1995'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 19:41:14

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:02:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:02:36
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 17:01:46
Coding entries removed.	Meghan York (b) (4)	23 Oct 2020 17:01:38
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:43:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:43:51
	(b) (4)	
Data point term sent to Coder	System	15 Sep 2020 19:42:35
User entered 'Flonase'	Meghan York (b) (4)	15 Sep 2020 19:42:04
	(b) (4)	

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'seasonal allergies'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		02 Dec 2020 16:05:43
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'actual dose was not specified ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:49:47
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 03:34:44
User entered 'I'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		28 Oct 2020 16:42:45
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Subject did not specify actual dose ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:02:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:01:38
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:11:47
User entered 'tablet (TABLET)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'spray' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:01:38
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		28 Oct 2020 16:48:41
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'now correct ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:01:46
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:01:38
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:11:58
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 1995'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 19:42:04

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: FORTESTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:37:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:37:31
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: FORTESTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:36:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:36:50
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 20:36:22
User closed query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	System	19 Oct 2020 20:35:30
Query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' answered with 'CORRECTED' (Site from System).	Jami Wagner (b) (4)	19 Oct 2020 20:35:30
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 20:35:18
User entered 'FORTESTA' reason for change: Data Entry Error	Jami Wagner (b) (4)	19 Oct 2020 20:35:12
	(b) (4)	

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:27:39
User entered 'foretaste'	System Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:37 15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		28 Oct 2020 16:42:33
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'now added to MH' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:03:09
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:16:46
User entered 'hypogonadism'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '10'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).		02 Dec 2020 19:21:04
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'this is the correct administration for this medication ' (Site from DM).	Meghan York (b) (4)	01 Dec 2020 20:50:26
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 03:57:28
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Jami Wagner (b) (4)	19 Oct 2020 20:35:12
User entered 'Oral (ORAL)'	(b) (4)	
	Meghan York (b) (4)	15 Sep 2020 19:43:09
	(b) (4)	

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 2016'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 19:43:09

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:45:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:45:44
Data point term sent to Coder	System	15 Sep 2020 19:44:38
User entered 'Imitrex'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'migraines'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '100'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'as needed (PRN)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 2000'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 19:43:49

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:46:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:46:47
Data point term sent to Coder	System	15 Sep 2020 19:45:53
User entered 'probiotic'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).		02 Dec 2020 16:53:55
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4)	01 Dec 2020 20:50:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 20:50:40
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).		24 Nov 2020 03:58:38
User entered 'No (N)'	Meghan York (b) (4)	15 Sep 2020 19:45:32
	(b) (4)	

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'general health'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		29 Jan 2021 04:05:05
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'actual dose unknown ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:08:07
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 tablet." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:20:39
User entered 'I'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'tablet (TABLET)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 2019'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 19:45:32

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B 12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:47:50
Data point term sent to Coder	System	15 Sep 2020 19:46:55
User entered 'Vitamin B-12'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'general health'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		28 Oct 2020 16:49:20
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Subject did not specify actual dose for this medication ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 17:03:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:19:29
User entered 'I'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		02 Dec 2020 16:06:09
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'actual dose was not specified ' (Site from DM).	Meghan York (b) (4) (b) (4)	01 Dec 2020 20:51:14
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 03:59:13
User entered 'tablet (TABLET)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'un UNK 2020'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 19:46:13

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 22:43:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 22:43:47
Data point term sent to Coder	System	02 Dec 2020 22:43:03
Coding entries removed.	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:42:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:03:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:03:46
Data point term sent to Coder	System	13 Nov 2020 17:03:14
User entered 'Tylenol'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query '1. "Per DM CLR: Please update the condition to include the location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match		07 Dec 2020 19:54:17
2. Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AFTER SECOND VACCINATION in eDiary. Please note that this CM was given at Day 4 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification."		
' (Site from DM).		
Query '1. "Per DM CLR: Please update the condition to include the location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:43:19
2. Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AFTER SECOND VACCINATION in eDiary. Please note that this CM was given at Day 4 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification."		
' answered with 'Subject reported pain for day 4. Not an AE. Solicited Event. ' (Site from DM).		
User entered 'INJECTION SITE PAIN AFTER SECOND VACCINATION' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:42:12

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '975'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).		29 Jan 2021 04:09:22
Query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:08:37
User entered 'once (ONCE)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:08:28
User opened query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:27:49
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '3 Oct 2020'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '3 Oct 2020'	Meghan York (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).		29 Jan 2021 04:09:27
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'Subject did not report this to the eDiary but this is the reason for taking this medication when the subject was contacted ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:10:53
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:27:29
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User entered empty.	System	25 Jan 2021 19:08:28
User entered '1'	System	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User entered empty.	System	25 Jan 2021 19:08:28
User entered '1'	System	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:28:49
User entered empty.	System	25 Jan 2021 19:08:28
User entered '804 (804)'	System	13 Nov 2020 17:02:23

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med indication for AE #2. Please reconcile and correct response in AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:18:02
Query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med indication for AE #2. Please reconcile and correct response in AE eCRF as appropriate. ' answered with 'corrected on AE page' (Site from DM).	Meghan York (b) (4)	25 Jan 2021 19:11:24
User opened query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med indication for AE #2. Please reconcile and correct response in AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:19:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 07:37:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 07:37:00
Data point term sent to Coder	System	17 Nov 2020 21:59:12
User entered 'phenergan'	Meghan York (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		07 Dec 2020 19:55:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'now added to AE page ' (Site from DM).	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:46:28
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:11:12
User entered 'intermittent neausea'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '25'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'as needed (PRN)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '13 Oct 2020'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	02 Dec 2020 22:44:01
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '13 Oct 2020' reason for change: Data Entry Error	Meghan York (b) (4)	02 Dec 2020 22:44:01
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User entered empty.	System	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User entered empty.	System	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:18
User entered empty.	System	17 Nov 2020 21:59:00

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:53:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:53:03
Data point term sent to Coder	System	20 Nov 2020 20:52:32
User entered 'tylenol'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'injection site pain'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '325'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'three times daily (TID)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '3 Oct 2020'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '3 Oct 2020'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).		29 Jan 2021 17:50:02
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'subject did not report this to the eDiary, but this is the reason the medication was taken when the subject was contacted ' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:13:21
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as UNSOLICITED event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:28:21
User entered 'Yes (Y)'	Jill York (b) (4)	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User entered '3'	System	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User entered '1'	System	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:45
User entered '804 (804)'	System	20 Nov 2020 20:51:37

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User closed query 'Protanix has not been added. It may be confused with another med of similar lettering.' (Site from CRA).		21 Apr 2021 17:45:04
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:05:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:05:47
Data point term sent to Coder	System	07 Apr 2021 16:19:09
Query 'Protanix has not been added. It may be confused with another med of similar lettering.' answered with 'this is the medication according to the subject ' (Site from CRA).	Jill York (b) (4)	07 Apr 2021 16:18:58
DataPoint Un-verified.	Jill York (b) (4)	07 Apr 2021 16:18:21
Coding entries removed.	Jill York (b) (4)	07 Apr 2021 16:18:21
User entered 'PROTONIX' reason for change: Data Entry Error	Jill York (b) (4)	07 Apr 2021 16:18:21

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:59:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:59:50
User opened query 'Protanix has not been added. It may be confused with another med of similar lettering.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 23:53:14
User closed query 'Please add to con med source document page if appropriate.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 23:53:14
Query 'Please add to con med source document page if appropriate.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 19:59:59
Data point term sent to Coder	System	22 Feb 2021 19:58:42
Coding entries removed.	Jill York (b) (4)	22 Feb 2021 19:58:29
User opened query 'Please add to con med source document page if appropriate.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 16:55:35
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 11:01:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 11:01:08
Data point term sent to Coder	System	25 Jan 2021 19:14:42

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EAB) (1725)

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US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Meghan York (b) (4)	25 Jan 2021 19:13:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:12:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:12:47
Data point term sent to Coder	System	17 Dec 2020 18:47:30
User entered 'PROTANIX' reason for change: Data Entry Error	Meghan York (b) (4)	17 Dec 2020 18:47:24
User entered 'SUBJECT IS NOW TAKING PROTANIX 40MG A DAY FOR AN ULCER.'	Meghan York (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:17
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).		25 Feb 2021 08:54:19
User closed query 'Per DM CLR: Please note, there is a medical condition if DUODENAL ULCER. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. ' (Site from DM).		25 Feb 2021 08:53:21
DataPoint Un-verified.	Jill York (b) (4)	22 Feb 2021 19:58:29
User entered 'duodenal ulcer' reason for change:	Jill York (b) (4)	22 Feb 2021 19:58:29
Data Entry Error		
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'corrected ' (Site from DM).	Jill York (b) (4)	22 Feb 2021 19:55:33
Query 'Per DM CLR: Please note, there is a medical condition if DUODENAL ULCER. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. ' answered with 'corrected ' (Site from DM).	Jill York (b) (4)	22 Feb 2021 19:55:27
User opened query 'Per DM CLR: Please note, there is a medical condition if DUODENAL ULCER. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:27:51

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 15:26:30
User closed query 'Per DM CLR: Please update the indication to specify the type of ULCER (e.g. gastric ulcer, pressure ulcer etc.). Reconile with AE eCRF and update as appropriate. ' (Site from DM).		16 Feb 2021 16:53:18
Query 'Per DM CLR: Please update the indication to specify the type of ULCER (e.g. gastric ulcer, pressure ulcer etc.). Reconile with AE eCRF and update as appropriate. ' answered with 'corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	29 Jan 2021 04:11:31
User entered 'ULCER (type unknown)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	25 Jan 2021 19:13:57
User opened query 'Per DM CLR: Please update the indication to specify the type of ULCER (e.g. gastric ulcer, pressure ulcer etc.). Reconile with AE eCRF and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:13:50
User entered 'ulcer'	Meghan York (b) (4) (b) (4)	25 Jan 2021 14:25:14
		17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:20
User entered '40'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:22
User entered 'mg (mg)'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:26
User entered empty.	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:29
User entered 'once daily (QD)'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:33
User entered empty.	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	16 Feb 2021 16:53:45
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:40
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:37
User entered 'Oral (ORAL)'	Meghan York (b) (4)	17 Dec 2020 18:46:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:43
User entered empty.	Meghan York (b) (4)	17 Dec 2020 18:46:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:53:51
User entered '22 Oct 2020'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:53
User entered '0'	Meghan York (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		12 Apr 2021 14:08:40
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data now corrected ' (Site from DM).	Jill York (b) (4)	07 Apr 2021 16:23:45
DataPoint Un-verified.	Jill York (b) (4)	07 Apr 2021 16:23:13
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	07 Apr 2021 16:23:13
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:56:03
DataPoint Verified.		16 Feb 2021 16:53:55
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:25:41
DataPoint Un-verified.	Jill York (b) (4)	07 Apr 2021 16:23:13
User entered '22 Oct 2020' reason for change: Data Entry Error	Jill York (b) (4)	07 Apr 2021 16:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 16:53:57
User entered empty.	Meghan York (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:54:02
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 18:46:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 18:46:54
User entered 'No (N)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:54
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 18:46:47
User entered empty.	Meghan York (b) (4) (b) (4)	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User entered '1'	System	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User entered '1'	System	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:30:50
User entered '804 (804)'	System	17 Dec 2020 18:46:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:25:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:15:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 16:15:42
Data point term sent to Coder	System	07 Apr 2021 16:11:57
User entered 'phenergan'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'nausea'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '25'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'mg (mg)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'once (ONCE)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Oral (ORAL)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered empty.	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '13 Oct 2020'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '0'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'No (N)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered '13 Oct 2020'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 22:25:41
User entered 'Yes (Y)'	Jill York (b) (4)	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User entered empty.	System	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User entered empty.	System	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:20
User entered empty.	System	07 Apr 2021 16:11:56

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: PYRIDOXINE HYDROCHLORIDE, PRODUCTSYNONYM: VITAMIN B6 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:25:43
Data point term sent to Coder	System	21 Apr 2021 17:11:30
User entered 'vitamin B6'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'general health'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '50'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'mg (mg)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'once daily (QD)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Oral (ORAL)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'un UNK 2020'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '0'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Yes (Y)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:11:22

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 06:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:12:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:45:26
Data point term sent to Coder	System	21 Apr 2021 17:13:32
User entered 'testosterone'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'hormone replacement'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '2'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Other (OTHER)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'applications'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'once daily (QD)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Transdermal (TRANSDERMAL)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'I'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Yes (Y)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:12:44

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:45:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 17:27:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 17:27:29
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 17:14:33
User entered 'tylenol'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'unspecified pain'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '650'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'mg (mg)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'as needed (PRN)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Oral (ORAL)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'un UNK 2020'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '0'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Yes (Y)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:13:47

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 07:12:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:12:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:45:26
Data point term sent to Coder	System	21 Apr 2021 17:16:34
User entered 'sodium chloride'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Yes (Y)'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'prophylaxis dehydration'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '500'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'mL (mL)'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'once daily (QD)'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '0'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:15:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 17:15:53
User entered 'No (N)' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 17:15:53
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:15:46
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User entered '1'	System	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User entered '1'	System	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:29
User entered '804 (804)'	System	21 Apr 2021 17:15:46

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:35:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:35:55
Data point term sent to Coder	System	21 Apr 2021 17:17:35
User entered 'pantoprazole sodium'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'ulcer'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '250'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'mL (mL)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'once daily (QD)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered empty.	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '0'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:45:26
User entered 'No (N)'	Jill York (b) (4)	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User entered '1'	System	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User entered '1'	System	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:20:35
User entered '804 (804)'	System	21 Apr 2021 17:17:16

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:21:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:43
DataPoint Un-verified.	Jill York (b) (4)	21 Apr 2021 15:25:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	21 Apr 2021 15:25:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:23:15
User closed query 'Please enter Concomitant Procedures' (Site from CRA).		20 Apr 2021 20:23:07
Query 'Please enter Concomitant Procedures' answered with 'NO DATA IS FOUND FOR A YESS RESPONSE.' (Site from CRA).	Lisa Jackson (b) (4)	19 Apr 2021 14:40:09
DataPoint Un-verified.	Lisa Jackson (b) (4)	19 Apr 2021 14:39:28
User entered 'No (N)' reason for change: Data Entry Error	Lisa Jackson (b) (4)	19 Apr 2021 14:39:28
User opened query 'Please enter Concomitant Procedures' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:44:19
DataPoint Verified.		12 Apr 2021 16:42:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Jill York (b) (4)	07 Apr 2021 16:24:36
User entered 'No (N)'	Jami Wagner (b) (4)	18 Mar 2021 21:19:18

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 15:33:28

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'CT abdomen and pelvis with contrast'	Jill York (b) (4)	21 Apr 2021 15:33:28

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'Adverse Event (AE)'	Jill York (b) (4)	21 Apr 2021 15:33:28

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:21:56

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered empty.	Jill York (b) (4)	21 Apr 2021 15:33:28

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:21:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:45
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 15:34:31

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:45
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'EGD'	Jill York (b) (4)	21 Apr 2021 15:34:31

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:45
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'Adverse Event (AE)'	Jill York (b) (4)	21 Apr 2021 15:34:31

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:21:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:45
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered empty.	Jill York (b) (4)	21 Apr 2021 15:34:31

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:21:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered '23 Oct 2020'	Jill York (b) (4)	21 Apr 2021 15:34:53

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'colonoscopy'	Jill York (b) (4)	21 Apr 2021 15:34:53

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered 'Adverse Event (AE)'	Jill York (b) (4)	21 Apr 2021 15:34:53

US3142268

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:21:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:51
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:17
User entered empty.	Jill York (b) (4)	21 Apr 2021 15:34:53

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:37
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:37
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:43:01
User entered '26/Oct/2020 16:55'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:43:04
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered '1'		26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:37
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered '04/Nov/2020 12:23'	System	04 Nov 2020 17:23:56

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
Reviewed for Safety.		23 Feb 2021 17:17:03
User entered 'I'		04 Nov 2020 17:23:56

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:37
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered '23/Nov/2020 12:11'	System	23 Nov 2020 17:11:42

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
Reviewed for Safety.		23 Feb 2021 17:17:03
User entered '1'		23 Nov 2020 17:11:42

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:37
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered '23/Feb/2021 12:17'	System	23 Feb 2021 17:17:35

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered 'I'		23 Feb 2021 17:17:35

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4)	11 Nov 2020 21:39:16
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Death

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:39:37
DataPoint Verified.		26 Oct 2020 20:55:13
Reviewed for Safety.		26 Oct 2020 20:54:46
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered '19/Mar/2021 06:42'	System	19 Mar 2021 13:42:30

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:26
User entered 'I'		19 Mar 2021 13:42:30

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:12
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'USA-US064-2020-MRNA-1273-P301000003'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:16
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:15
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:19
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:21
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Yes (Y)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:23
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:25
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:27
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'No (N)'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:33
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Ripley'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:36
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Hollister'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:39:20
User entered '4190 East Woodmen Road Suite 210'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '2855 Dublin Blvd' reason for change:	Jill York (b) (4)	18 Mar 2021 23:42:24
Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 21:39:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 20:55:13
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:54:46
User entered '4190 East Woodmen Road Suite 210'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:39
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered 'Colorado Springs'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:13
User entered empty.	System	19 Mar 2021 13:42:30
User entered 'Colorado'	Jill York (b) (4)	18 Mar 2021 23:42:24

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 11:22:18
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:40:15
User entered '80920'	System	19 Mar 2021 13:42:30
Un-reviewed for Safety.	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Un-verified.	Jill York (b) (4)	18 Mar 2021 23:42:24
User entered '80918' reason for change: Data Entry Error	Jill York (b) (4)	18 Mar 2021 23:42:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:39:42
Reviewed for Safety.		26 Oct 2020 20:55:13
User entered '80920'	System	26 Oct 2020 20:54:46

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 21:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:39:43
Reviewed for Safety.		04 Nov 2020 17:23:35
User entered 'US'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Apr 2021 11:22:11
User entered '5'	System	19 Mar 2021 13:42:30
User entered '4'	System	23 Feb 2021 17:17:35
User entered '3'	System	23 Nov 2020 17:11:42
User entered '2'	System	04 Nov 2020 17:23:56
User entered '1'	System	26 Oct 2020 20:55:20

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:09:01
User entered '22/Apr/2021 07:22'	System	22 Apr 2021 11:22:11

US3142268

Folder: SAE USA-US064-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:45:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:09:01
Reviewed for Safety.		22 Apr 2021 11:22:18
User entered '1'		22 Apr 2021 11:22:11