

US3282113 (Prod: Foothill Family Clinic-South Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:25:43

All time stamps listed in this document are displayed in GMT

US3282113

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

[Participant ID](#)

US3282113

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

US3282113

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN SEP 2018
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)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3282113

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	SEASONAL ALLERGIES
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 (5)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	INTERMITTENT MIDSTERNAL CHEST PAIN, CARDIAC
Start date (dd MMM yyyy)	UN UNK 2010
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)	02 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Condition	UNKNOWN DERMAL FILLER TO FACE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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)	15:12 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:12
Height (xxx.x)	71.0 in
Weight (xxx.x)	214.6 lb
BMI (xxx.x)	29.99321 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) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 00:22:18

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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

MICROBIOLOGY LAB WITH
ABOUT 65 OTHER STAFF
MEMBERS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 00:22:18

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 191382

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) 20 Feb 2021 00:22:19

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

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)	16 OCT 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:12
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

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)	16 OCT 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 16:59
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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) 16 OCT 2020

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

Treatment Date and Time (derived) 16 OCT 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	15:33 (24 HR)
Collection date and time (derived)	16 OCT 2020 15:33

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	16 OCT 2020 15:30
Nasopharyngeal Swab 2	No		

US3282113

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

97.6 °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

16 OCT 2020 17:04

PC Open Date & Time

16 OCT 2020 16:40

PC Close Date & Time

16 OCT 2020 19:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

16 OCT 2020 20:05

PC Close Date & Time

17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

97.1 °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

18 OCT 2020 01:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

97.3 °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

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

99.3 °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

19 OCT 2020 12:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

97.9 °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

20 OCT 2020 19:15

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

97.2 °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

21 OCT 2020 12:09

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

97.2 °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

22 OCT 2020 17:04

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

16 OCT 2020 17:06

PC Open Date & Time

16 OCT 2020 16:40

PC Close Date & Time

16 OCT 2020 19:10

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

16 OCT 2020 20:05

PC Close Date & Time

17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

18 OCT 2020 01:42

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

18 OCT 2020 19:33

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

19 OCT 2020 12:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

20 OCT 2020 19:15

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

21 OCT 2020 12:10

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

22 OCT 2020 17:04

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 17:07
PC Open Date & Time	16 OCT 2020 16:40
PC Close Date & Time	16 OCT 2020 19:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 OCT 2020 20:05

PC Close Date & Time

17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 01:43
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

50 of 2312

EAB) (1725)

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:34
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

52 of 2312

EAB) (1725)

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:51
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2312

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 19:16
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

56 of 2312

EAB) (1725)

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 12:11
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 17:05
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

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

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 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

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

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)	19 NOV 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:08
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 13:07
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

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) 19 NOV 2020

What was the treatment time? (00:00-23:59) 12:37 (24 HR)

Treatment Date and Time (derived) 19 NOV 2020 12:37

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

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 NOV 2020
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	19 NOV 2020 11:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	19 NOV 2020 11:45
Nasopharyngeal Swab 2	No		

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

98.5 °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

19 NOV 2020 13:08

PC Open Date & Time

19 NOV 2020 12:57

PC Close Date & Time

19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

97.9 °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

19 NOV 2020 16:29

PC Open Date & Time

19 NOV 2020 16:22

PC Close Date & Time

20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

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

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

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

21 NOV 2020 18:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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):

PC Time Stamp

22 NOV 2020 12:14

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

98.3 °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

23 NOV 2020 12:35

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

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

24 NOV 2020 21:59

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

97.0 °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

25 NOV 2020 16:34

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

19 NOV 2020 13:10

PC Open Date & Time

19 NOV 2020 12:57

PC Close Date & Time

19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

19 NOV 2020 16:30

PC Open Date & Time

19 NOV 2020 16:22

PC Close Date & Time

20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

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

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

21 NOV 2020 18:04

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

22 NOV 2020 12:15

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

23 NOV 2020 12:35

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

24 NOV 2020 21:59

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

25 NOV 2020 16:34

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 13:10
PC Open Date & Time	19 NOV 2020 12:57
PC Close Date & Time	19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 16:31
PC Open Date & Time	19 NOV 2020 16:22
PC Close Date & Time	20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

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EAB) (1725)

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US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

Yes ☐

PC Time stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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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EAB) (1725)

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 18:05
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 12:15
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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EAB) (1725)

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 12:36
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 22:01
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 16:35
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:18

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 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

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 11:14
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3282113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3282113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 DEC 2020
Collection time (00:00-23:59)	11:32 (24 HR)
Collection date and time (derived)	14 DEC 2020 11:32

US3282113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 00:22:19

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 61
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 18:18:31
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 68
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 00:15:51
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 75
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 00:03:30
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 16:01:36
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 checked="" 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 checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 14:13:45
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 19:41:06
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

26 JAN 2021 12:15:58

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

02 FEB 2021 12:17:38

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

07 FEB 2021 20:32:18

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 00:23:22
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

21 FEB 2021 00:05:13

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

28 FEB 2021 20:07:01

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

10 MAR 2021 06:28:51

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 18:14:56
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 18:12:40
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

31 MAR 2021 18:20:06

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

04 APR 2021 00:53:59

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

13 APR 2021 12:47:27

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

20 APR 2021 15:58:46

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☒

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

25 APR 2021 10:09:15

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐ 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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3282113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:25:43

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
Yes	No	28 FEB 2021 20:07:39

US3282113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:05:40

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:09:45

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:09:45

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 19:09:45

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:09:45

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 15:24:02

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 15:24:02

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3282113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3282113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

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.

US3282113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3282113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3282113

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:25:43

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"/>

US3282113

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:25:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	22 JAN 2021
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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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US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Date of updated informed consent (dd MMM yyyy) 22 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) 22 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 _____

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00-23:59)	13:28 (24 HR)
Collection date and time (derived)	22 JAN 2021 13:28

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	13:24
Collection Date and Time (derived)	22 JAN 2021 13:24

US3282113

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 00:57:41

Generated On: 09 Jun 2021 16:25:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID	USA-US201-2020-MRNA-1273-P30 1000001
Adverse event	CORONARY ARTERY DISEASE
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)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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 type="radio"/> Grade 4 <input checked="" 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)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	25 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 00:57:40

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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 checked="" type="radio"/> Recovered/Resolved <input 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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

SUBJECT CONTACTED SITE
STAFF TO INFORM OF RECENT
HOSPITALIZATION. THE
SUBJECT EXPERIENCED CHEST
PAIN ON 23OCT2020. THE
SUBJECT PRESENTED TO
HOSPITAL WHERE STRESS TEST
IDENTIFIED BLOCKED
CORONARY ARTERY. THE
SUBJECT WAS HOSPITALIZED
UNTIL 25OCT2020.
CONCOMITANT MEDICATIONS
WERE STARTED AND A
CORONARY BYPASS SURGERY
HAS BEEN SCHEDULED FOR
02NOV2020. THE SUBJECT IS
SCHEDULED TO RECEIVE DOSE
2 OF STUDY INTERVENTION ON
20NOV2020.

EKG ON 30OCT2020 REVEALED
SINUS BRADYCARDIA, SEPTAL
INFARCT, NONSPECIFIC ST AND
T WAVE ABNORMALITY.

CT CORONARY ANGIOGRAPHY
ON 23OCT2020 REVEALED
SEVERE 100% OCCLUSION OF
THE MID LAD AT THE
BIFURCATION OF THE FIRST
DIAGONAL ARTERY,
MODERATE STENOSIS OF THE
PROXIMAL RCA,
INCOMPLETELY EVALUATED
CYSTIC LESION WITHIN LEFT

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

KIDNEY.
CARDIAC CATHETERIZATION
ON 27OCT2020 REVEALED CTO
OF LAD WITH COLLETERALS
FROM RCA AND FLOW
VISUALIZED IN LAD ON RCC
INJECTION, NON DOMINANT
SMALL LCX, MILD RCA
DISEASE.

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

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID	
Adverse event	CONGESTIVE HEART FAILURE
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)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Recovered/Resolved <input 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID	USA-US201-2020-MRNA-1273-P30 1000001
Adverse event	MULTIPLE SUBSEGMENTAL PULMONARY EMBOLI
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)	6 NOV 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)	8 DEC 2020
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 type="radio"/> Grade 4 <input checked="" 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)	6 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

PT WAS DISCHARGED FROM
HOSPITAL ON 06NOV2020
FOLLOWING HOSPITALIZATION
FOR CABG PROCEDURE. LATER
THAT EVENING, PT
EXPERIENCED SHORTNESS OF
BREATH AND WAS SEEN IN
EMERGENCY DEPARTMENT. PT
WAS DIAGNOSED WITH
PULMONARY
THROMBOEMBOLISM AND
WAS ADMITTED TO HOSPITAL.
PT WAS STARTED ON IV
HEPARIN, THEN TRANSITIONED
TO ELIQUIS. PT WAS
DISCHARGED TO HOME ON
10NOV2020.
PT WAS ADMITTED TO
HOSPITAL ON 02NOV2020 FOR
CABG.

FOLLOW UP: CTPA REVEALED
MULTIPLE SUBSEGMENTAL
PULMONARY EMBOLI WITH
SMALL TO MODERATELY
SIZED BILATERAL PLEURAL
EFFUSIONS. BILATERAL LE US
REVEALED NO EVIDENCE OF A
DEEP OR SUPERFICIAL VENOUS
THROMBOSIS IN LOWER
EXTREMITIES.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID

Adverse event

POST CORONARY ARTERY
BYPASS GRAFT PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID

Adverse event

WORSENING OF MIDSTERNAL
CHEST PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID	
Adverse event	CYSTIC LESION WITHIN LEFT KIDNEY
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)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

AEID

Adverse event

BILATERAL PLEURAL
EFFUSIONS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

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 ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 00:57:40

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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	INCIDENTAL FINDING DURING HOSPITALIZATION FOR PULMONARY EMBOLI.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 2017	
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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 85

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 (2)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 2017	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration .4

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 (3)

Data signed: (b) (4) 01 Apr 2021 19:09:42

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	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)		UN SEP 2018
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)		2
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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication IPRATROPIUM BROMIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 34

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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2015	
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) _____		
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 (5)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

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 (5)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	6 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

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 (6)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	24 OCT 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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 (7)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	24 OCT 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 (8)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	24 OCT 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 (9)

Data signed: (b) (4) 01 Apr 2021 19:09:42

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Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY
THROMBOEMBOLISM

Dose per administration UNK

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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 (9)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 checked="" 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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN NOV 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 (10)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY
THROMBOEMBOLISM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
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) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ANTI-COAGULATION POST CABG

Dose per administration 81

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 (11)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)	UN NOV 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 (12)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST CABG PAIN

Dose per administration 5

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 (12)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 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 (13)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA PHOPHYLAXIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

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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US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication SODIUM CHLORIDE FLUSH

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 checked="" 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)		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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication SODIUM CHLORIDE 0.9% BOLUS

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 333.55

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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US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE SUBSEGMENTAL
PULMONARY EMBOLI

Dose per administration 5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 01 Apr 2021 19:09:42

Generated On: 09 Jun 2021 16:25:43

	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)		17 NOV 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 19:09:43

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 NOV 2020	CORONARY ARTERY BYPASS GRAFT	Adverse Event	
30 OCT 2020	EKG	Adverse Event	
23 OCT 2020	CT CORONARY ANGIOGRAPHY	Adverse Event	
27 OCT 2020	CARDIAC CATHETERIZATION	Adverse Event	

US3282113

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:25:43

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

US3282113

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/OCT/2020 16:23
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/NOV/2020 14:28
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 19:05
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 11:31
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/DEC/2020 16:21
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/DEC/2020 14:23
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 01 Apr 2021 19:09:44

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/DEC/2020 10:39
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

US3282113 (Prod: Foothill Family Clinic-South Clinic)

US3282113

Form: Participant Creation

Generated On: 09 Jun 2021 16:25:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'US3282113'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:29

US3282113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:30

US3282113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Clinic (Clinic)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'SCRN'	System	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:31

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '66'	(b) (4) Jessica Shaw(b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'YEARS'	System	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '66'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Male (M)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'I'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Oct 2020'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2020'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Amendment 4 (4)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 22:44:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	16 Oct 2020 22:44:59
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 22:44:53
User entered empty.	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:30

US3282113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'l'	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:25:43

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:25:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (u) (4) (b) (4)	17 Oct 2020 01:13:34

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:35
Data point term sent to Coder	System	17 Oct 2020 01:14:34
User entered 'hyperlipidemia'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un UNK 2017'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (u) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2017'	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2017'	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
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).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:08:27
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. ' answered with 'updated conmeds' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 15:18:35
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)	23 Oct 2020 07:10:26
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
Data point term sent to Coder	System	17 Oct 2020 01:14:34
User entered 'hypothyroidism'	dylan owen (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un UNK 2017'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	17 Oct 2020 01:17:09
User entered 'Yes (Y)' reason for change: Data Entry Error	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:17:09
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	17 Oct 2020 01:14:23
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2017'	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2017'	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Oct 2020 09:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:36
Data point term sent to Coder	System	17 Oct 2020 01:15:34
User entered 'benign prostatic hyperplasia'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un Sep 2018'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen(b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (u) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Sep 2018'	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2018'	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
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.	(b) (4) Coder Import (b) (4)	17 Oct 2020 09:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:36
Data point term sent to Coder	System	17 Oct 2020 01:17:35
User entered 'seasonal allergies'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un UNK 2015'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2015'	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2015'	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 17:23:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:23:01
Data point term sent to Coder	System	24 Nov 2020 15:51:21
User closed query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	System	24 Nov 2020 15:51:17
Query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' answered with 'clarified' (Site from System).	Jessica Shaw (b) (4)	24 Nov 2020 15:51:17
User entered 'INTERMITTENT MIDSTERNAL CHEST PAIN, cardiac' reason for change: Data Entry Error	Jessica Shaw (b) (4)	24 Nov 2020 15:51:03
User opened query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:30:05
Data point term sent to Coder	System	23 Nov 2020 18:53:23
User entered 'intermittent midsternal chest pain'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un UNK 2010'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '02 Nov 2020'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2010'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2010'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Nov 2020'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2020'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: 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) (4), (b) (6)	16 Dec 2020 13:29:44
Query 'Per CDM: 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. ' answered with 'no conmed for sleep apnea' (Site from DM).	Jessica Shaw (b) (4)	01 Dec 2020 01:47:41
User opened query 'Per CDM: 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)	26 Nov 2020 16:21:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:07
Data point term sent to Coder	System	23 Nov 2020 18:57:31
User entered 'obstructive sleep apnea'	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'un UNK 2014'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2014'	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2014'	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 06:18:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 06:18:28
Data point term sent to Coder	System	23 Mar 2021 20:21:37
User entered 'unknown dermal filler to face'	Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'un UNK 2014'	(b) (4) Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'un UNK 2014'	(b) (4) Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered '0'	(b) (4) Jessica Shaw (b) (4)	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2014'	System	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2014'	System	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'Jan 2014'	System	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '2014'	System	23 Mar 2021 20:21:20

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen(b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '15:12'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '16 Oct 2020 15:12'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '71.0' in	(b) (4) dylan owen(b) (4)	17 Oct 2020 01:18:59
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '214.6' lb	(b) (4) dylan owen (b) (4)	17 Oct 2020 01:18:59
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '29.99321'	System	17 Oct 2020 01:18:59
DataPoint set to visible.	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'kg/m2'	System	17 Oct 2020 01:18:59
DataPoint set to visible.	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:02:07
Query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	22 Oct 2020 15:16:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User opened query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:59:35
User entered '98.7' F	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty; reason for change Data Entry Error	(b) (4) Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered 'Oral (Oral)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '62'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'bpm'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '16'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'breaths/min'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '124'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'mmHg'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '84'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'mmHg'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03

US3282113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:19:18

US3282113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:19:18

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'microbiology lab with about 65 other staff members'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'l'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '0'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Clinic (Clinic)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'VISIT1'	System	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '191382'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOIN (b) (4)	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4)	17 Oct 2020 01:24:08
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:44:53

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Pre-Dose (PREDOSE)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen(b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '15:12'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '16 Oct 2020 15:12'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '98.7' F	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Oral (Oral)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '62'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'bpm'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'breaths/min'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '124'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '84'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Post-Dose (POSTDOSE)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16:59'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '16 Oct 2020 16:59'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '97.6' F	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Oral (Oral)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '61'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'bpm'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'breaths/min'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '130'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '83'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:17

US3282113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:17

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16:20'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '16 Oct 2020 16:20'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'ONCE'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '15:33'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '16 Oct 2020 15:33'	System	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16 Oct 2020'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '15:30'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '16 Oct 2020 15:30'	System	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen(b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered empty.	System	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:41

US3282113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'I'	System	17 Oct 2020 01:27:41

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered 'Yes (Y)'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered '97.6'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered 'No (N)'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered '16 Oct 2020 17:04'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668' User entered 'Yes (Y)'	System	18 Oct 2020 07:41:31
	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668' User entered '97.1'	System	18 Oct 2020 07:41:31
	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668'	System	18 Oct 2020 07:41:31
User entered 'No (N)'	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668' User entered '18 Oct 2020 01:41'	System	18 Oct 2020 07:41:31
	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f' User entered 'Yes (Y)'	System	19 Oct 2020 01:32:56
	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f' User entered '97.3'	System	19 Oct 2020 01:32:56
	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f' User entered 'No (N)'	System	19 Oct 2020 01:32:56
	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f' User entered '18 Oct 2020 19:32'	System	19 Oct 2020 01:32:56
	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered 'Yes (Y)'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered '99.3'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered 'No (N)'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:27', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered '19 Oct 2020 12:50'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:14:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered 'Yes (Y)'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:14:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered '97.9'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered 'No (N)'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered '20 Oct 2020 19:15'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:33', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0' User entered 'Yes (Y)'	System	21 Oct 2020 18:09:50
	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0' User entered '97.2'	System	21 Oct 2020 18:09:50
	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0'	System	21 Oct 2020 18:09:50
User entered 'No (N)'	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0' User entered '21 Oct 2020 12:09'	System	21 Oct 2020 18:09:50
	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:03:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28' User entered 'Yes (Y)'	System	22 Oct 2020 23:04:18
	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28' User entered '97.2'	System	22 Oct 2020 23:04:18
	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28'	System	22 Oct 2020 23:04:18
User entered 'No (N)'	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28' User entered '22 Oct 2020 17:04'	System	22 Oct 2020 23:04:18
	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'No (N)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'No (N)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'None (1)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902' User entered '16 Oct 2020 17:06'	System	16 Oct 2020 23:06:09
	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631' User entered 'No (N)'	System	18 Oct 2020 07:42:37
	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631' User entered 'No (N)'	System	18 Oct 2020 07:42:37
	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'None (1)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631' User entered '18 Oct 2020 01:42'	System	18 Oct 2020 07:42:37
	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9'	System	19 Oct 2020 01:33:33
User entered 'None (1)'	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9' User entered 'No (N)'	System	19 Oct 2020 01:33:33
	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9' User entered 'No (N)'	System	19 Oct 2020 01:33:33
	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9'	System	19 Oct 2020 01:33:33
User entered 'None (1)'	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9' User entered '18 Oct 2020 19:33'	System	19 Oct 2020 01:33:33
	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd'	System	19 Oct 2020 18:51:02
User entered 'None (1)'	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered 'No (N)'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered 'No (N)'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered 'None (1)'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered '19 Oct 2020 12:50'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'None (1)'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'No (N)'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'No (N)'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'None (1)'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered '20 Oct 2020 19:15'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered 'None (1)'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered 'No (N)'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered 'No (N)'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered 'None (1)'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered '21 Oct 2020 12:10'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered 'None (1)'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered 'No (N)'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered 'No (N)'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered 'None (1)'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered '22 Oct 2020 17:04'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:07:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'No (N)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:07:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered '16 Oct 2020 17:07'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'No interference with activity (1)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'None (0)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'None (0)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'None (0)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'None (0)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'None (0)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered 'No (N)'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201' User entered '18 Oct 2020 01:43'	System	18 Oct 2020 07:43:47
	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'None (0)'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered 'No (N)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509' User entered '18 Oct 2020 19:34'	System	19 Oct 2020 01:34:49
	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'None (0)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'No (N)'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered '19 Oct 2020 12:51'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:53', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'None (0)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered 'No (N)'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82' User entered '20 Oct 2020 19:16'	System	21 Oct 2020 01:16:18
	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:33', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538' User entered 'None (0)'	System	21 Oct 2020 18:11:07
	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538' User entered 'None (0)'	System	21 Oct 2020 18:11:07
	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:11:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'No (N)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:11:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered '21 Oct 2020 12:11'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'No (N)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered '22 Oct 2020 17:05'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '23 Oct 2020'	(b) (4) Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	23 Oct 2020 15:18:47

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	23 Oct 2020 15:18:47

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '30 Oct 2020'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:08

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	09 Nov 2020 18:56:08

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '9 Nov 2020'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	09 Nov 2020 18:56:32

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	09 Nov 2020 18:56:32

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Clinic (Clinic)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'VISIT2'	System	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Pre-Dose (PREDOSE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11:08'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '19 Nov 2020 11:08'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '97.8' F	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Oral (Oral)'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '74'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'bpm'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '18'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'breaths/min'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '126'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '84'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Post-Dose (POSTDOSE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Nov 2020 19:54:40
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '13:07' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '19 Nov 2020 13:07'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '98.5' F reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '68' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'bpm'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '14' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'breaths/min'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '130' reason for change: Data Entry Error	(b) (4) dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '79' reason for change: Data Entry Error	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	(b) (4)	
	dylan owen (b) (4)	19 Nov 2020 19:54:40
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Nov 2020 00:45:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 00:45:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	20 Nov 2020 00:45:49
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 19:54:55
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:55
	(b) (4)	

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:54:55

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '12:37'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '19 Nov 2020 12:37'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'ONCE'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11:40'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '19 Nov 2020 11:40'	System	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '19 Nov 2020'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11:45'	(b) (4) dylan owen (u) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '19 Nov 2020 11:45'	System	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'No (N)'	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered empty.	System	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) dylan owen(b) (4) (b) (4)	19 Nov 2020 19:58:01

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'I'	System	19 Nov 2020 19:58:01

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be' User entered 'Yes (Y)'	System	19 Nov 2020 20:08:57
	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be' User entered '98.5'	System	19 Nov 2020 20:08:57
	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be'	System	19 Nov 2020 20:08:57
User entered 'No (N)'	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:53', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be' User entered '19 Nov 2020 13:08'	System	19 Nov 2020 20:08:57
	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:28:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c' User entered 'Yes (Y)'	System	19 Nov 2020 23:29:13
	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:28:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c' User entered '97.9'	System	19 Nov 2020 23:29:13
	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c' User entered 'No (N)'	System	19 Nov 2020 23:29:13
	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c' User entered '19 Nov 2020 16:29'	System	19 Nov 2020 23:29:13
	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f' User entered 'Yes (Y)'	System	22 Nov 2020 01:03:39
	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f' User entered '97.4'	System	22 Nov 2020 01:03:39
	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f' User entered 'No (N)'	System	22 Nov 2020 01:03:39
	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f' User entered '21 Nov 2020 18:03'	System	22 Nov 2020 01:03:39
	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1' User entered 'Yes (Y)'	System	22 Nov 2020 19:14:47
	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1' User entered '97.9'	System	22 Nov 2020 19:14:47
	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1' User entered 'No (N)'	System	22 Nov 2020 19:14:47
	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1' User entered '22 Nov 2020 12:14'	System	22 Nov 2020 19:14:47
	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:34:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935' User entered 'Yes (Y)'	System	23 Nov 2020 19:35:14
	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935' User entered '98.3'	System	23 Nov 2020 19:35:14
	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935' User entered 'No (N)'	System	23 Nov 2020 19:35:14
	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935' User entered '23 Nov 2020 12:35'	System	23 Nov 2020 19:35:14
	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:58:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be' User entered 'Yes (Y)'	System	25 Nov 2020 04:59:18
	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be' User entered '98.2'	System	25 Nov 2020 04:59:18
	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be'	System	25 Nov 2020 04:59:18
User entered 'No (N)'	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be' User entered '24 Nov 2020 21:59'	System	25 Nov 2020 04:59:18
	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e12e5230-32fc-44c9-a72e-d69c21f7edf0' User entered 'Yes (Y)'	System	25 Nov 2020 23:34:33
	System	25 Nov 2020 23:34:33

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e12e5230-32fc-44c9-a72e-d69c21f7edf0' User entered '97.0'	System	25 Nov 2020 23:34:33
	System	25 Nov 2020 23:34:33

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e12e5230-32fc-44c9-a72e-d69c21f7edf0'	System	25 Nov 2020 23:34:33
User entered 'No (N)'	System	25 Nov 2020 23:34:33

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e12e5230-32fc-44c9-a72e-d69c21f7edf0' User entered '25 Nov 2020 16:34'	System	25 Nov 2020 23:34:33
	System	25 Nov 2020 23:34:33

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90' User entered 'No (N)'	System	19 Nov 2020 20:10:10
	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90' User entered 'No (N)'	System	19 Nov 2020 20:10:10
	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'None (1)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90' User entered '19 Nov 2020 13:10'	System	19 Nov 2020 20:10:10
	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a'	System	19 Nov 2020 23:30:49
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered 'No (N)'	System	19 Nov 2020 23:30:49
	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered 'No (N)'	System	19 Nov 2020 23:30:49
	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered 'None (1)'	System	19 Nov 2020 23:30:49
	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered '19 Nov 2020 16:30'	System	19 Nov 2020 23:30:49
	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd'	System	22 Nov 2020 01:04:19
User entered 'Does not interfere with activity (2)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd' User entered 'No (N)'	System	22 Nov 2020 01:04:19
	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd' User entered 'No (N)'	System	22 Nov 2020 01:04:19
	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd'	System	22 Nov 2020 01:04:19
User entered 'None (1)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd' User entered '21 Nov 2020 18:04'	System	22 Nov 2020 01:04:19
	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:52', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e'	System	22 Nov 2020 19:15:11
User entered 'None (1)'	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:55', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e' User entered 'No (N)'	System	22 Nov 2020 19:15:11
	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e' User entered 'No (N)'	System	22 Nov 2020 19:15:11
	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e'	System	22 Nov 2020 19:15:11
User entered 'None (1)'	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e' User entered '22 Nov 2020 12:15'	System	22 Nov 2020 19:15:11
	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered 'None (1)'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered 'No (N)'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered 'No (N)'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered 'None (1)'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered '23 Nov 2020 12:35'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'None (1)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5' User entered 'No (N)'	System	25 Nov 2020 04:59:56
	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5' User entered 'No (N)'	System	25 Nov 2020 04:59:56
	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'None (1)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5' User entered '24 Nov 2020 21:59'	System	25 Nov 2020 04:59:56
	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '23a877e8-3e78-4d3a-bdf7-fb9f8d87c6e7'	System	25 Nov 2020 23:34:54
User entered 'None (1)'	System	25 Nov 2020 23:34:54

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '23a877e8-3e78-4d3a-bdf7-fb9f8d87c6e7' User entered 'No (N)'	System	25 Nov 2020 23:34:54
	System	25 Nov 2020 23:34:54

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '23a877e8-3e78-4d3a-bdf7-fb9f8d87c6e7' User entered 'No (N)'	System	25 Nov 2020 23:34:54
	System	25 Nov 2020 23:34:54

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '23a877e8-3e78-4d3a-bdf7-fb9f8d87c6e7'	System	25 Nov 2020 23:34:54
User entered 'None (1)'	System	25 Nov 2020 23:34:54

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '23a877e8-3e78-4d3a-bdf7-fb9f8d87c6e7' User entered '25 Nov 2020 16:34'	System	25 Nov 2020 23:34:54
	System	25 Nov 2020 23:34:54

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'None (0)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered 'No (N)'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered '19 Nov 2020 13:10'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:52', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3' User entered 'None (0)'	System	19 Nov 2020 23:31:39
	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3' User entered 'None (0)'	System	19 Nov 2020 23:31:39
	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'No (N)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3' User entered '19 Nov 2020 16:31'	System	19 Nov 2020 23:31:39
	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:32', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'None (0)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered 'No (N)'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3' User entered '21 Nov 2020 18:05'	System	22 Nov 2020 01:05:16
	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:24', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642' User entered 'None (0)'	System	22 Nov 2020 19:15:44
	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'No (N)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered '22 Nov 2020 12:15'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:59', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'None (0)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered 'No (N)'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0' User entered '23 Nov 2020 12:36'	System	23 Nov 2020 19:36:19
	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:37', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'None (0)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered 'No (N)'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:01:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8' User entered '24 Nov 2020 22:01'	System	25 Nov 2020 05:01:04
	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:34:59', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'None (0)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered 'No (N)'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-25T16:35:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9234d71c-49d0-4643-94d6-99465f3eac19' User entered '25 Nov 2020 16:35'	System	25 Nov 2020 23:35:19
	System	25 Nov 2020 23:35:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:26:00
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	30 Nov 2020 23:54:48

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '27 Nov 2020'	(b) (4) Jessica Shaw (b) (4)	30 Nov 2020 23:54:48

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	30 Nov 2020 23:54:48

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	30 Nov 2020 23:54:48

US3282113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	30 Nov 2020 23:54:52

US3282113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	30 Nov 2020 23:54:52

US3282113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	04 Dec 2020 18:03:14

US3282113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '4 Dec 2020'	(b) (4) Jessica Shaw (b) (4)	04 Dec 2020 18:03:14

US3282113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	04 Dec 2020 18:03:14

US3282113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Jessica Shaw (b) (4)	04 Dec 2020 18:03:14

US3282113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	04 Dec 2020 18:03:19

US3282113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	04 Dec 2020 18:03:19

US3282113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	14 Dec 2020 16:15:05

US3282113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11 Dec 2020'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	14 Dec 2020 16:15:05

US3282113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	14 Dec 2020 16:15:05

US3282113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Rachel Pugmire (b) (4) (b) (4)	14 Dec 2020 16:15:05

US3282113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Rachel Pugmire (b) (4) (b) (4)	14 Dec 2020 16:15:09

US3282113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	14 Dec 2020 16:15:09

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Madison Elli (b) (4)	14 Dec 2020 18:59:14

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, "saliva collection mistakenly associated with US3282113 instead of correctly associated with US3282115". Please review the Preclarus data and update Preclarus to match PPD sample for Day 3- 14DEC2020 and Day 5- 16DEC2020 to correct Subject ID and correct visit label as appropriate. Also keep the query open till the updates are made. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 11:06:42
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, "saliva collection mistakenly associated with US3282113 instead of correctly associated with US3282115". Please review the Preclarus data and update Preclarus to match PPD sample for Day 3- 14DEC2020 and Day 5- 16DEC2020 to correct Subject ID and correct visit label as appropriate. Also keep the query open till the updates are made. Thank you.' answered with 'Request to change was submitted to PPD, no response.' (Site from DM).	Jessica Shaw (b) (4)	11 Jan 2021 21:33:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, "saliva collection mistakenly associated with US3282113 instead of correctly associated with US3282115". Please review the Preclarus data and update Preclarus to match PPD sample for Day 3- 14DEC2020 and Day 5- 16DEC2020 to correct Subject ID and correct visit label as appropriate. Also keep the query open till the updates are made. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 02:22:44
User closed query 'Per GCL Lab Reconciliation: Saliva :Requery: Please confirm if the Illness visits were performed, if yes kindly add the saliva details, else clarify.Thanks' (Site from DM).		04 Jan 2021 05:53:44

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva :Requery: Please confirm if the Illness visits were performed, if yes kindly add the saliva details, else clarify.Thanks' answered with 'no illness visits performed for US3282113. saliva collection mistakenly associated with US3282113 instead of correctly associated with US3282115' (Site from DM).	Jessica Shaw (b) (4)	29 Dec 2020 14:41:48
User opened query 'Per GCL Lab Reconciliation: Saliva :Requery: Please confirm if the Illness visits were performed, if yes kindly add the saliva details, else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:23:13
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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)	29 Dec 2020 05:23:13
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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 'error, should be associated with US3282115. DCRF submitted.' (Site from DM).	Jessica Shaw (b) (4)	28 Dec 2020 14:36:23
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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)	24 Dec 2020 08:19:42
User entered '14 Dec 2020'	Madison Ellis (b) (4)	14 Dec 2020 18:59:14

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Clinic (Clinic)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 18:59:14

US3282113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'VISIT3'	System	14 Dec 2020 18:59:14

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '14 Dec 2020'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11:14'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '14 Dec 2020 11:14'	System	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '97.9' F	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Oral (Oral)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered empty.	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '74'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'bpm'	System	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '16'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'breaths/min'	System	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen(b) (4)	20 Feb 2021 00:22:19
User entered '124'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '77'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'mmHg'	System	14 Dec 2020 19:00:52

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36

US3282113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36

US3282113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:01:36

US3282113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '14 Dec 2020'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:01:36

US3282113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:02:24

US3282113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '14 Dec 2020'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:02:24

US3282113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered '11:32'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:02:24

US3282113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered '14 Dec 2020 11:32'	System	14 Dec 2020 19:02:24

US3282113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	20 Feb 2021 00:22:19
User entered 'Yes (Y)'	(b) (4) Madison Ellis (b) (4)	14 Dec 2020 19:02:39

US3282113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'I'	System	14 Dec 2020 19:02:39

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-16T18:18:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '232a1f52-fe72-4f78-a45c-ec8db9b85a5b' User entered 'No (N)'	System	17 Dec 2020 01:18:34
	System	17 Dec 2020 01:18:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-16T18:18:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '232a1f52-fe72-4f78-a45c-ec8db9b85a5b' User entered 'No (N)'	System	17 Dec 2020 01:18:34
	System	17 Dec 2020 01:18:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-16T18:18:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '232a1f52-fe72-4f78-a45c-ec8db9b85a5b' User entered '16 Dec 2020 18:18:31'	System	17 Dec 2020 01:18:34
	System	17 Dec 2020 01:18:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-20T00:15:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '728efd2d-ea8a-4d00-9441-e55055cd1678' User entered 'No (N)'	System	20 Dec 2020 07:15:53

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-20T00:15:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '728efd2d-ea8a-4d00-9441-e55055cd1678' User entered 'No (N)'	System	20 Dec 2020 07:15:53

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-20T00:15:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '728efd2d-ea8a-4d00-9441-e55055cd1678' User entered '20 Dec 2020 00:15:51'	System	20 Dec 2020 07:15:53
	System	20 Dec 2020 07:15:53

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-27T00:03:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '99d6266b-7225-43d1-8487-d84e716371ec' User entered 'No (N)'	System	27 Dec 2020 07:03:32

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-27T00:03:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '99d6266b-7225-43d1-8487-d84e716371ec' User entered 'No (N)'	System	27 Dec 2020 07:03:32

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-12-27T00:03:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '99d6266b-7225-43d1-8487-d84e716371ec' User entered '27 Dec 2020 00:03:30'	System	27 Dec 2020 07:03:32
	System	27 Dec 2020 07:03:32

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-04T16:01:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '49a62680-4511-4230-88f2-70edfd003e63' User entered 'No (N)'	System	04 Jan 2021 23:02:28
	System	04 Jan 2021 23:02:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-04T16:01:32', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '49a62680-4511-4230-88f2-70edfd003e63'	System	04 Jan 2021 23:02:28
User entered 'No (N)'	System	04 Jan 2021 23:02:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-04T16:01:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '49a62680-4511-4230-88f2-70edfd003e63' User entered '04 Jan 2021 16:01:36'	System	04 Jan 2021 23:02:28
	System	04 Jan 2021 23:02:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-12T14:13:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e9644e63-2eaa-4cd1-91bf-b5b348d15603' User entered 'No (N)'	System	12 Jan 2021 21:14:03
	System	12 Jan 2021 21:14:03

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-12T14:13:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e9644e63-2eaa-4cd1-91bf-b5b348d15603' User entered 'Yes (Y)'	System	12 Jan 2021 21:14:03
	System	12 Jan 2021 21:14:03

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-12T14:13:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e9644e63-2eaa-4cd1-91bf-b5b348d15603'	System	12 Jan 2021 21:14:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Jan 2021 21:14:03

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-12T14:13:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e9644e63-2eaa-4cd1-91bf-b5b348d15603' User entered '12 Jan 2021 14:13:45'	System	12 Jan 2021 21:14:03
	System	12 Jan 2021 21:14:03

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-18T19:40:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f885c06f-080d-484a-936c-ad725f063f04'	System	19 Jan 2021 02:41:09
User entered 'No (N)'	System	19 Jan 2021 02:41:09

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-18T19:41:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f885c06f-080d-484a-936c-ad725f063f04'	System	19 Jan 2021 02:41:09
User entered 'No (N)'	System	19 Jan 2021 02:41:09

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-18T19:41:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f885c06f-080d-484a-936c-ad725f063f04'	System	19 Jan 2021 02:41:09
User entered '18 Jan 2021 19:41:06'	System	19 Jan 2021 02:41:09

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-26T12:15:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '21754453-e671-4f34-9e9c-27eda2814542' User entered 'No (N)'	System	26 Jan 2021 20:22:37
	System	26 Jan 2021 20:22:37

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-26T12:15:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '21754453-e671-4f34-9e9c-27eda2814542'	System	26 Jan 2021 20:22:37
User entered 'No (N)'	System	26 Jan 2021 20:22:37

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-01-26T12:15:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '21754453-e671-4f34-9e9c-27eda2814542' User entered '26 Jan 2021 12:15:58'	System	26 Jan 2021 20:22:37
	System	26 Jan 2021 20:22:37

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-02T12:17:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ad31fc00-ae91-44c8-9eee-8947499ad6ce' User entered 'No (N)'	System	02 Feb 2021 19:17:41
	System	02 Feb 2021 19:17:41

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-02T12:17:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ad31fc00-ae91-44c8-9eee-8947499ad6ce' User entered 'No (N)'	System	02 Feb 2021 19:17:41

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-02T12:17:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ad31fc00-ae91-44c8-9eee-8947499ad6ce' User entered '02 Feb 2021 12:17:38'	System	02 Feb 2021 19:17:41
	System	02 Feb 2021 19:17:41

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-07T20:31:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1b2619bb-efcc-45ce-b572-5f48f22543cd' User entered 'No (N)'	System	08 Feb 2021 03:32:20
	System	08 Feb 2021 03:32:20

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-07T20:32:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1b2619bb-efcc-45ce-b572-5f48f22543cd' User entered 'No (N)'	System	08 Feb 2021 03:32:20

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-07T20:32:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1b2619bb-efcc-45ce-b572-5f48f22543cd' User entered '07 Feb 2021 20:32:18'	System	08 Feb 2021 03:32:20
	System	08 Feb 2021 03:32:20

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-14T00:23:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c6a93029-1fb1-47a4-a1e3-da15ff98a85c' User entered 'No (N)'	System	14 Feb 2021 07:23:25

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-14T00:23:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c6a93029-1fb1-47a4-a1e3-da15ff98a85c' User entered 'No (N)'	System	14 Feb 2021 07:23:25

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-14T00:23:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c6a93029-1fb1-47a4-a1e3-da15ff98a85c' User entered '14 Feb 2021 00:23:22'	System	14 Feb 2021 07:23:25
	System	14 Feb 2021 07:23:25

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-21T00:05:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '01df2e4d-849b-4185-b309-358d7b6d7983' User entered 'No (N)'	System	21 Feb 2021 07:05:16

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-21T00:05:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '01df2e4d-849b-4185-b309-358d7b6d7983' User entered 'No (N)'	System	21 Feb 2021 07:05:16

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-21T00:05:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '01df2e4d-849b-4185-b309-358d7b6d7983'	System	21 Feb 2021 07:05:16
User entered '21 Feb 2021 00:05:13'	System	21 Feb 2021 07:05:16

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:06:47-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '25b9726a-21cb-446b-97a4-d18605b55cbc' User entered 'No (N)'	System	01 Mar 2021 03:11:34
	System	01 Mar 2021 03:11:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:06:55-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '25b9726a-21cb-446b-97a4-d18605b55cbc' User entered 'No (N)'	System	01 Mar 2021 03:11:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:07:01-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '25b9726a-21cb-446b-97a4-d18605b55cbc' User entered '28 Feb 2021 20:07:01'	System	01 Mar 2021 03:11:34
	System	01 Mar 2021 03:11:34

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-10T06:28:35-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '98b049e1-1cd5-4e3e-87e2-f4908a4eae64' User entered 'No (N)'	System	10 Mar 2021 13:28:54
	System	10 Mar 2021 13:28:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-10T06:28:45-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '98b049e1-1cd5-4e3e-87e2-f4908a4eae64'	System	10 Mar 2021 13:28:54
User entered 'No (N)'	System	10 Mar 2021 13:28:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-10T06:28:51-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '98b049e1-1cd5-4e3e-87e2-f4908a4eae64' User entered '10 Mar 2021 06:28:51'	System	10 Mar 2021 13:28:54
	System	10 Mar 2021 13:28:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-17T18:14:26-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '00e84844-6204-4c30-86b0-0e09f49966b6'	System	18 Mar 2021 00:14:59
User entered 'No (N)'	System	18 Mar 2021 00:14:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-17T18:14:52-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '00e84844-6204-4c30-86b0-0e09f49966b6'	System	18 Mar 2021 00:14:59
User entered 'No (N)'	System	18 Mar 2021 00:14:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-17T18:14:56-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '00e84844-6204-4c30-86b0-0e09f49966b6' User entered '17 Mar 2021 18:14:56'	System	18 Mar 2021 00:14:59
	System	18 Mar 2021 00:14:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-24T18:12:32-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '62c82f41-4b5b-4fb4-accf-5596c60985d0' User entered 'No (N)'	System	25 Mar 2021 00:13:57
	System	25 Mar 2021 00:13:57

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-24T18:12:36-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '62c82f41-4b5b-4fb4-accf-5596c60985d0'	System	25 Mar 2021 00:13:57
User entered 'No (N)'	System	25 Mar 2021 00:13:57

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-24T18:12:40-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '62c82f41-4b5b-4fb4-accf-5596c60985d0' User entered '24 Mar 2021 18:12:40'	System	25 Mar 2021 00:13:57
	System	25 Mar 2021 00:13:57

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-31T18:19:52-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3c058e0e-4e2f-4982-9050-4bcc92129b3d' User entered 'No (N)'	System	01 Apr 2021 00:20:08
	System	01 Apr 2021 00:20:08

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-31T18:20:00-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3c058e0e-4e2f-4982-9050-4bcc92129b3d' User entered 'No (N)'	System	01 Apr 2021 00:20:08
	System	01 Apr 2021 00:20:08

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-03-31T18:20:06-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3c058e0e-4e2f-4982-9050-4bcc92129b3d' User entered '31 Mar 2021 18:20:06'	System	01 Apr 2021 00:20:08
	System	01 Apr 2021 00:20:08

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-04T00:53:47-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '14017a5b-0da6-4e42-b998-1e5a9edeb8df' User entered 'No (N)'	System	04 Apr 2021 06:54:05
	System	04 Apr 2021 06:54:05

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-04T00:53:55-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '14017a5b-0da6-4e42-b998-1e5a9edeb8df' User entered 'No (N)'	System	04 Apr 2021 06:54:05

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-04T00:53:59-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '14017a5b-0da6-4e42-b998-1e5a9edeb8df' User entered '04 Apr 2021 00:53:59'	System	04 Apr 2021 06:54:05
	System	04 Apr 2021 06:54:05

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-13T12:47:18-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '766ecb0f-2073-4aa7-bafd-c9c2944cecf'	System	13 Apr 2021 18:47:28
User entered 'No (N)'	System	13 Apr 2021 18:47:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-13T12:47:22-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '766ecb0f-2073-4aa7-bafd-c9c2944cecf'	System	13 Apr 2021 18:47:28
User entered 'No (N)'	System	13 Apr 2021 18:47:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-13T12:47:27-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '766ecb0f-2073-4aa7-bafd-c9c2944cecf'	System	13 Apr 2021 18:47:28
User entered '13 Apr 2021 12:47:27'	System	13 Apr 2021 18:47:28

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-20T15:58:36-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dbf4d280-ef56-451b-ae5c-54dfed07eeee' User entered 'No (N)'	System	20 Apr 2021 21:58:52

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-20T15:58:42-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dbf4d280-ef56-451b-ae5c-54dfed07eeee' User entered 'No (N)'	System	20 Apr 2021 21:58:52

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-20T15:58:46-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dbf4d280-ef56-451b-ae5c-54dfed07eeee' User entered '20 Apr 2021 15:58:46'	System	20 Apr 2021 21:58:52
	System	20 Apr 2021 21:58:52

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-25T10:09:08-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1312a6ee-8043-4a44-ab08-a957902e1474' User entered 'No (N)'	System	25 Apr 2021 16:10:54
	System	25 Apr 2021 16:10:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-25T10:09:12-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1312a6ee-8043-4a44-ab08-a957902e1474' User entered 'No (N)'	System	25 Apr 2021 16:10:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-04-25T10:09:15-06:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1312a6ee-8043-4a44-ab08-a957902e1474'	System	25 Apr 2021 16:10:54
User entered '25 Apr 2021 10:09:15'	System	25 Apr 2021 16:10:54

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:25:43

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)	25 Apr 2021 12:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:07:21-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '7b5f88a6-3f40-46c7-8499-fe837a1c431d'	System	01 Mar 2021 03:12:19
User entered 'Yes (Y)'	System	01 Mar 2021 03:12:19

US3282113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:25:43

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:07:31-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '7b5f88a6-3f40-46c7-8499-fe837a1c431d'	System	01 Mar 2021 03:12:19
User entered 'No (N)'	System	01 Mar 2021 03:12:19

US3282113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:25:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:56:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2021-02-28T20:07:39-07:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '7b5f88a6-3f40-46c7-8499-fe837a1c431d' User entered '28 Feb 2021 20:07:39'	System	01 Mar 2021 03:12:19
	System	01 Mar 2021 03:12:19

US3282113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	12 Jan 2021 00:45:05

US3282113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered '11 Jan 2021'	(b) (4) Jessica Shaw (b) (4)	12 Jan 2021 00:45:05

US3282113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	12 Jan 2021 00:45:05

US3282113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered empty.	(b) (4) Jessica Shaw (b) (4)	12 Jan 2021 00:45:05

US3282113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User signature succeeded.	Shane Christensen (b) (4)	25 Mar 2021 22:05:40
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	12 Jan 2021 00:45:10

US3282113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:13:36
User entered 'l'	System	12 Jan 2021 00:45:10

US3282113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	15 Feb 2021 19:48:10

US3282113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '15 Feb 2021'	(b) (4) Jessica Shaw (b) (4)	15 Feb 2021 19:48:10

US3282113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	15 Feb 2021 19:48:10

US3282113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered empty.	(b) (4) Jessica Shaw (b) (4)	15 Feb 2021 19:48:10

US3282113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	15 Feb 2021 19:48:15

US3282113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User entered 'l'	System	15 Feb 2021 19:48:15

US3282113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) Madison Ellis (b) (4)	16 Mar 2021 20:09:48

US3282113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '16 Mar 2021'	(b) (4) Madison Elli (b) (4)	16 Mar 2021 20:09:48

US3282113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Madison Elli (b) (4)	16 Mar 2021 20:09:48

US3282113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered empty.	(b) (4) Madison Elli (b) (4)	16 Mar 2021 20:09:48

US3282113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) Madison Elli (b) (4)	16 Mar 2021 20:09:56

US3282113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:18:46
User entered 'l'	System	16 Mar 2021 20:09:56

US3282113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	19 Apr 2021 15:24:02
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	15 Apr 2021 21:42:31

US3282113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	19 Apr 2021 15:24:02
User entered '15 Apr 2021'	(b) (4) Jessica Shaw (b) (4)	15 Apr 2021 21:42:31

US3282113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	19 Apr 2021 15:24:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica Shaw (b) (4)	15 Apr 2021 21:42:31

US3282113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	19 Apr 2021 15:24:02
User entered empty.	(b) (4) Jessica Shaw (b) (4)	15 Apr 2021 21:42:31

US3282113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	19 Apr 2021 15:24:02
User entered 'Yes (Y)'	(b) (4) Jessica Shaw (b) (4)	15 Apr 2021 21:42:36

US3282113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Apr 2021 21:42:36

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:36:55

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:36:55

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:36:55

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 21:36:55

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '0'	(b) (4) Jessica Shaw (b) (4)	22 Mar 2021 20:36:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:53:44

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Jessica Shaw (b) (4)	22 Mar 2021 20:36:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:53:44

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered empty.	System	22 Jan 2021 21:37:24

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:40

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:40

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '13:28'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:40

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '22 Jan 2021 13:28'	System	22 Jan 2021 21:37:40

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:54

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:54

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '13:24'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:37:54

US3282113

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:16:03
User entered '22 Jan 2021 13:24'	System	22 Jan 2021 21:37:54

US3282113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:25:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:05:49
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:36:50
User entered 'Yes (Y)'	(b) (4), (b) (6) Jessica Shaw (b) (4)	28 Oct 2020 14:23:56

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
Reviewed for Safety.		28 Oct 2020 20:22:59
User entered	System	28 Oct 2020 20:22:53
'USA-US201-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 20:22:53

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4)	04 Nov 2020 15:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 15:40:30
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 15:25:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 15:25:29
Data point term sent to Coder	System	04 Nov 2020 15:23:51
Coding entries removed.	Jessica Shaw (b) (4)	04 Nov 2020 15:23:04
User entered 'coronary artery disease' reason for change: New Information	Jessica Shaw (b) (4)	04 Nov 2020 15:23:04
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery occlusion, LLT: Coronary artery occlusion - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:03:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:03:58
Data point term sent to Coder	System	28 Oct 2020 14:31:16
User entered 'Blocked Coronary Artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	(b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	(b) (4)	28 Oct 2020 14:30:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 18:06:54
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).		04 Nov 2020 14:29:27
User entered empty.	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Grade 4 (Grade 4)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	(b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'I'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '23 Oct 2020'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:27:59
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'initial discharge date=25Oct2020. Pt plans to be readmitted, and will update us once discharged.' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 14:51:38
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:23:48
User entered '25 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	(b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	(b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. Else, please provide the date of second dose of IP.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 18:24:52
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. Else, please provide the date of second dose of IP.' answered with 'ePIP was submitted and medical monitor approved. Second dose received 19Nov2020' (Site from Safety).	Jessica Shaw (b) (4)	30 Dec 2020 23:47:00
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. Else, please provide the date of second dose of IP.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 21:33:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'None (NONE)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	(b) (4) (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'l'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'l'	(b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
User closed query 'PV Query: Thank you for confirming that the event is not expected to fully resolve. Please consider if the event should be considered resolved with sequelae.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:33:15
Query 'PV Query: Thank you for confirming that the event is not expected to fully resolve. Please consider if the event should be considered resolved with sequelae.' answered with 'new diagnosis of coronary artery disease, expected not to resolve, but with no additional sequelae.' (Site from Safety).	Jessica Shaw (b) (4)	14 Dec 2020 16:15:52
User opened query 'PV Query: Thank you for confirming that the event is not expected to fully resolve. Please consider if the event should be considered resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 11:26:20
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).		05 Dec 2020 16:20:52
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 expected to resolve' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:18:41
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)	03 Dec 2020 15:14:51
DataPoint Verified.		05 Nov 2020 21:37:12
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).		05 Nov 2020 14:28:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
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 '"coronary artery disease" not expected to resolve, but procedure of coronary artery bypass graft will be performed for this condition.' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 21:59:11
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)	04 Nov 2020 14:26:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	(b) (4)	28 Oct 2020 14:30:38
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
User closed query 'Per DM CLR: SAE Narrative = SINUS BRADYCARDIA, SEPTAL INFARCT, NONSPECIFIC ST AND T WAVE ABNORMALITY. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:52:31
User closed query 'Per DM CLR: SAE Narrative = CARDIAC CATHETERIZATION ON 27OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		25 Jan 2021 14:50:52
User closed query 'Per DM CLR: SAE Narrative = CT CORONARY ANGIOGRAPHY ON 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		25 Jan 2021 14:50:45
User closed query 'Per DM CLR: SAE Narrative = EKG ON 30OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		25 Jan 2021 14:50:41
Query 'Per DM CLR: SAE Narrative = CARDIAC CATHETERIZATION ON 27OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Jessica Shaw (b) (4)	22 Jan 2021 17:30:17
Query 'Per DM CLR: SAE Narrative = CT CORONARY ANGIOGRAPHY ON 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Jessica Shaw (b) (4)	22 Jan 2021 17:29:48

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SINUS BRADYCARDIA, SEPTAL INFARCT, NONSPECIFIC ST AND T WAVE ABNORMALITY. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'secondary findings related to SAE event coronary artery disease' (Site from DM).	Jessica Shaw (b) (4)	22 Jan 2021 17:28:50
Query 'Per DM CLR: SAE Narrative = EKG ON 30OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Jessica Shaw (b) (4)	22 Jan 2021 17:28:06
User opened query 'Per DM CLR: SAE Narrative = CARDIAC CATHETERIZATION ON 27OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:34:02
User opened query 'Per DM CLR: SAE Narrative = CT CORONARY ANGIOGRAPHY ON 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:33:58
User opened query 'Per DM CLR: SAE Narrative = SINUS BRADYCARDIA, SEPTAL INFARCT, NONSPECIFIC ST AND T WAVE ABNORMALITY. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:33:52
User opened query 'Per DM CLR: SAE Narrative = EKG ON 30OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:33:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:39:12
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).	(b) (4), (b) (6)	30 Nov 2020 14:41:34

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	30 Nov 2020 14:41:31
User closed query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		30 Nov 2020 14:41:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'already added' (Site from Safety).	Jessica Shaw(b) (4)	25 Nov 2020 19:46:41
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 'previously answered' (Site from Safety).	Jessica Shaw(b) (4)	25 Nov 2020 19:46:31
Query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records were sent' (Site from Safety).	Jessica Shaw(b) (4)	25 Nov 2020 19:46:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Sit from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:34:40
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).		25 Nov 2020 11:34:12
User opened query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		25 Nov 2020 11:33:52

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[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	24 Nov 2020 16:30:42
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).		24 Nov 2020 16:30:35
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		24 Nov 2020 16:30:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent via email.' (Site from Safety).	Jessica Shaw (b) (4)	23 Nov 2020 22:36:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'laboratory and diagnostic test results added to narrative.' (Site from Safety).	Jessica Shaw (b) (4)	23 Nov 2020 19:37:02

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE STAFF TO INFORM OF RECENT HOSPITALIZATION. THE SUBJECT EXPERIENCED CHEST PAIN ON 23OCT2020. THE SUBJECT PRESENTED TO HOSPITAL WHERE STRESS TEST IDENTIFIED BLOCKED CORONARY ARTERY. THE SUBJECT WAS HOSPITALIZED UNTIL 25OCT2020. CONCOMITANT MEDICATIONS WERE STARTED AND A CORONARY BYPASS SURGERY HAS BEEN SCHEDULED FOR 02NOV2020. THE SUBJECT IS SCHEDULED TO RECEIVE DOSE 2 OF STUDY INTERVENTION ON 20NOV2020. EKG ON 30OCT2020 REVEALED SINUS BRADYCARDIA, SEPTAL INFARCT, NONSPECIFIC ST AND T WAVE ABNORMALITY. CT CORONARY ANGIOGRAPHY ON 23OCT2020 REVEALED SEVERE 100% OCCLUSION OF THE MID LAD AT THE BIFURCATION OF THE FIRST DIAGONAL ARTERY, MODERATE STENOSIS OF THE PROXIMAL RCA, INCOMPLETELY EVALUATED CYSTIC LESION WITHIN LEFT KIDNEY. Cardiac catheterization on 27Oct2020 revealed CTO of LAD with collaterals from RCA and flow visualized in LAD on RCC injection, non dominant small LCX, mild RCA disease.' reason for change: Data Entry Error DataPoint Un-verified.	Jessica Shaw(b) (4) [REDACTED]	23 Nov 2020 19:36:00
	Jessica Shaw(b) (4) [REDACTED]	23 Nov 2020 19:19:35

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE STAFF TO INFORM OF RECENT HOSPITALIZATION. THE SUBJECT EXPERIENCED CHEST PAIN ON 23OCT2020. THE SUBJECT PRESENTED TO HOSPITAL WHERE STRESS TEST IDENTIFIED BLOCKED CORONARY ARTERY. THE SUBJECT WAS HOSPITALIZED UNTIL 25OCT2020. CONCOMITANT MEDICATIONS WERE STARTED AND A CORONARY BYPASS SURGERY HAS BEEN SCHEDULED FOR 02NOV2020. THE SUBJECT IS SCHEDULED TO RECEIVE DOSE 2 OF STUDY INTERVENTION ON 20NOV2020. EKG on 30Oct2020 revealed sinus bradycardia, septal infarct, nonspecific ST and T wave abnormality. CT coronary angiography on 23Oct2020 revealed severe 100% occlusion of the mid LAD at the bifurcation of the first diagonal artery, moderate stenosis of the proximal RCA, incompletely evaluated cystic lesion within left kidney.' reason for change: Data Entry Error	Jessica Shaw(b) (4)	23 Nov 2020 19:19:35
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 'Novel Coronavirus (COVID-19) Antigen test done via swab on 30Oct2020. Result=negative.' (Site from Safety).	Jessica Shaw(b) (4)	23 Nov 2020 19:01:24
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)	13 Nov 2020 19:23:45
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)	13 Nov 2020 19:23:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:28:20
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).		05 Nov 2020 14:28:16
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).		05 Nov 2020 14:28:12
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'pt with ongoing medical history item of hyperlipidemia' (Site from Safety).	Jessica Shaw(b) (4)	04 Nov 2020 14:53:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'will update once records are received' (Site from Safety).	Jessica Shaw(b) (4)	04 Nov 2020 14:52:36
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 'will update once records are received' (Site from Safety).	Jessica Shaw(b) (4)	04 Nov 2020 14:52:09
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)	04 Nov 2020 14:27:34
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).		04 Nov 2020 14:25:51
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).		04 Nov 2020 14:25:18

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[Narrative](#)

Audit	User	Time (GMT)
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)	04 Nov 2020 14:24:40
User entered 'Subject contacted site staff to inform of Jessica Shaw recent hospitalization. The subject experienced chest pain on 23Oct2020. The subject presented to hospital where stress test identified blocked coronary artery. The subject was hospitalized until 25Oct2020. Concomitant medications were started and a coronary bypass surgery has been scheduled for 02Nov2020. The subject is scheduled to receive dose 2 of study intervention on 20Nov2020.'	(b) (4)	28 Oct 2020 14:30:38

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 14:30:38

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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 'I'	System	28 Oct 2020 14:30:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 14:30:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:39:41
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:52:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:52:30
Data point term sent to Coder	System	06 Nov 2020 00:52:05
User entered 'congestive heart failure'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:39:42
User entered 'Yes (Y)'	(b) (4) (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:39:44
User entered 'No (N)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:39:48
User entered 'No (N)'	(b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:39:50
User entered '23 Oct 2020'	Jessica Shaw (b) (4) (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:39:52
User entered empty.	(b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:39:55
User entered 'Yes (Y)'	(b) (4) (b) (4)	06 Nov 2020 00:51:30

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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)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:39:57
User entered empty.	(b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:39:58
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:40:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:40:03
User entered 'No (N)'	(b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 22:40:05
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:07
User entered '0'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:09
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:11
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:14
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:15
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:17
User entered empty.	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:18
User entered '0'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:20
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

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Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:22
User entered '0'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:24
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:25
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:27
User entered 'None (NONE)'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:31
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:34
User entered 'l'	Jessica Shaw(b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:36
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:41
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:40:43
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	18 Nov 2020 22:16:15
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:04:54
User entered 'USA-US201-2020-mRNA-1273-P301000001'		17 Nov 2020 19:04:50

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:04:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:11:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:11:51
Data point term sent to Coder	System	08 Dec 2020 17:46:43
DataPoint Un-verified.	Jessica Shaw (b) (4)	08 Dec 2020 17:45:54
	(b) (4)	
Coding entries removed.	Jessica Shaw (b) (4)	08 Dec 2020 17:45:54
	(b) (4)	
User entered 'multiple subsegmental pulmonary emboli' reason for change: Data Entry Error	Jessica Shaw (b) (4)	08 Dec 2020 17:45:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary thromboembolism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:50:46
Data point term sent to Coder	System	16 Nov 2020 18:50:27
User entered 'pulmonary thromboembolism'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09
	(b) (4)	

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:18
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:20
User entered 'No (N)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:21
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 DM).	(b) (4), (b) (6)	28 Apr 2021 10:17:27
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 'Original value correct' (Site from DM).	Madison Elli (b) (4)	23 Apr 2021 23:24:57
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:47:09
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 22:16:22
User entered '6 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:24
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:34:31
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).		14 Dec 2020 11:31:46
User entered empty.	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:50:12
DataPoint Un-verified.	Jessica Shaw (b) (4)	23 Dec 2020 16:32:16
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Dec 2020 16:32:16
DataPoint Verified.	(D) (4), (b) (6)	18 Nov 2020 22:16:26
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:50:14
DataPoint Un-verified.	Jessica Shaw(b) (4)	23 Dec 2020 16:32:16
User entered '8 Dec 2020' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Dec 2020 16:32:16
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).	(D) (4), (b) (6)	05 Dec 2020 16:19:30
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 'waiting for receipt of medical records' (Site from Safety).	Jessica Shaw(b) (4)	04 Dec 2020 17:19:28
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)	25 Nov 2020 11:35:56
DataPoint Verified.		18 Nov 2020 22:16:28
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:29
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:43
User entered 'Grade 4 (Grade 4)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:44
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:16:46
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:05
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:06
User entered 'I'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:09
User entered '6 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:10
User entered '10 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:14
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:17
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:18
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:20
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:21
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:22
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:24
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:25
User entered 'None (NONE)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

None

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:27
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
User closed query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis (Apixaban) after being discharged. Please update the concomitant medication logs accordingly. Thanks.' (Site from CRA).	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:50:23
Query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis (Apixaban) after being discharged. Please update the concomitant medication logs accordingly. Thanks.' answered with 'added to conmed pg' (Site from CRA).	Jessica Shaw (b) (4)	19 Nov 2020 00:10:43
User opened query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis (Apixaban) after being discharged. Please update the concomitant medication logs accordingly. Thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:21:50
Query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis after being discharged. Please update the concomitant medication logs accordingly. Thanks. ' canceled (Site from CRA).		18 Nov 2020 22:21:38
User opened query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis after being discharged. Please update the concomitant medication logs accordingly. Thanks. ' (Site from CRA).		18 Nov 2020 22:20:53
DataPoint Verified.		18 Nov 2020 22:17:29
User entered 'I'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:33
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:50:27
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).		28 Dec 2020 15:38:51
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 updated' (Site from Safety).	Jessica Shaw(b) (4)	23 Dec 2020 16:33:10
DataPoint Un-verified.	Jessica Shaw(b) (4)	23 Dec 2020 16:32:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Dec 2020 16:32:16
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)	14 Dec 2020 11:30:42
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).		05 Dec 2020 16:19:46
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 'waiting for receipt of medical records to confirm' (Site from Safety).	Jessica Shaw(b) (4)	04 Dec 2020 17:19:39
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)	25 Nov 2020 11:36:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	18 Nov 2020 22:17:38
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 18:50:09

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:50:43
User closed query 'PV Query: Please provide the results of any additional COVID-19 testing performed during the subsequent hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		15 Dec 2020 15:34:20
Query 'PV Query: Please provide the results of any additional COVID-19 testing performed during the subsequent hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'per pt, not done. not present on medical records.' (Site from Safety).	Jessica Shaw(b) (4)	14 Dec 2020 16:48:41
User opened query 'PV Query: Please provide the results of any additional COVID-19 testing performed during the subsequent hospital admission, including date of collection and type of testing. If no done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 11:33:38
User closed query 'PV Query: Please send a hospital discharge summary for the event of pulmonary thromboembolism with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.: ' (Site from Safety).		09 Dec 2020 14:22:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WAS DISCHARGED FROM HOSPITAL ON 06NOV2020 FOLLOWING HOSPITALIZATION FOR CABG PROCEDURE. LATER THAT EVENING, PT EXPERIENCED SHORTNESS OF BREATH AND WAS SEEN IN EMERGENCY DEPARTMENT. PT WAS DIAGNOSED WITH PULMONARY THROMBOEMBOLISM AND WAS ADMITTED TO HOSPITAL. PT WAS STARTED ON IV HEPARIN, THEN TRANSITIONED TO ELIQUIS. PT WAS DISCHARGED TO HOME ON 10NOV2020. PT WAS ADMITTED TO HOSPITAL ON 02NOV2020 FOR CABG. follow up: CTPA revealed multiple subsegmental pulmonary emboli with small to moderately sized bilateral pleural effusions. bilateral LE US revealed no evidence of a deep or superficial venous thrombosis in lower extremities.' reason for change: Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 19:05:05
Query 'PV Query: Please send a hospital discharge summary for the event of pulmonary thromboembolism with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.: ' answered with 'sent 08Dec2020' (Site from Safety).	Jessica Shaw(b) (4)	08 Dec 2020 18:57:13
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).	(b) (4), (b) (6)	05 Dec 2020 16:20:40
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).		05 Dec 2020 16:20:37
User closed query 'PV Query: Please provide the results of diagnostic testing that confirmed the diagnosis of pulmonary embolism' (Site from Safety).		05 Dec 2020 16:20:27
User closed query 'PV Query: Please provide admission date for CABG hospitalization.' (Site from Safety).		05 Dec 2020 16:20:16

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add treatment medications, heparin and apixaban to the concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	05 Dec 2020 16:20:11
Query 'PV Query: Please add treatment medications, heparin and apixaban to the concomitant medication eCRF.' answered with 'medications are added' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:42:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'waiting on records' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:22:30
Query 'PV Query: Please provide the results of diagnostic testing that confirmed the diagnosis of pulmonary embolism' answered with 'waiting on records' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:22:23
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 'awaiting receipt of records' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:22:09
Query 'PV Query: Please provide admission date for CABG hospitalization.' answered with 'added' (Site from Safety).	Jessica Shaw (b) (4)	04 Dec 2020 17:22:01
DataPoint Un-verified.	Jessica Shaw (b) (4)	04 Dec 2020 17:21:54
User entered 'PT WAS DISCHARGED FROM HOSPITAL ON 06NOV2020 FOLLOWING HOSPITALIZATION FOR CABG PROCEDURE. LATER THAT EVENING, PT EXPERIENCED SHORTNESS OF BREATH AND WAS SEEN IN EMERGENCY DEPARTMENT. PT WAS DIAGNOSED WITH PULMONARY THROMBOEMBOLISM AND WAS ADMITTED TO HOSPITAL. PT WAS STARTED ON IV HEPARIN, THEN TRANSITIONED TO ELIQUIS. PT WAS DISCHARGED TO HOME ON 10NOV2020. Pt was admitted to hospital on 02NOV2020 for CABG.' reason for change: Data Entry Error	Jessica Shaw (b) (4)	04 Dec 2020 17:21:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[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)	03 Dec 2020 15:13:35
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).		03 Dec 2020 15:12:53
User opened query 'PV Query: Please provide the results of diagnostic testing that confirmed the diagnosis of pulmonary embolism' (Site from Safety)		03 Dec 2020 15:12:30
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).		02 Dec 2020 13:26:45
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).		02 Dec 2020 13:26:44
User closed query 'PV Query: Please provide any additional treatment given (in addition to heparin and apixaban) 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 Dec 2020 13:26:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'will update when medical records received' (Site from Safety).	Jessica Shaw (b) (4)	01 Dec 2020 19:55:41
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 'will update when medical records received' (Site from Safety).	Jessica Shaw (b) (4)	01 Dec 2020 19:55:38

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any additional treatment given (in addition to heparin and apixaban) 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 'will update when medical records received' (Site from Safety).	Jessica Shaw (b) (4)	01 Dec 2020 19:55:31
User opened query 'PV Query: Please provide admission date for CABG hospitalization.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:37:27
User opened query 'PV Query: Please add treatment medications, heparin and apixaban to the concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:37:06
User opened query 'PV Query: Please provide any additional treatment given (in addition to heparin and apixaban) 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)	25 Nov 2020 11:36:49
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)	25 Nov 2020 11:36:15
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)	25 Nov 2020 11:35:37
User opened query 'PV Query: Please send a hospital discharge summary for the event of pulmonary thromboembolism with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 11:35:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt was discharged from hospital on 06Nov2020 following hospitalization for CABG procedure. Later that evening, pt experienced shortness of breath and was seen in emergency department. Pt was diagnosed with pulmonary thromboembolism and was admitted to hospital. Pt was started on IV heparin, then transitioned to Eliquis. Pt was discharged to home on 10Nov2020.'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	16 Nov 2020 18:50:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 18:50:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 18:50:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:01:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:01:51
Data point term sent to Coder	System	16 Nov 2020 20:31:13
User entered 'post coronary artery bypass graft pain'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:05
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:07
User entered 'No (N)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:09
User entered 'No (N)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:11
User entered '2 Nov 2020'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:13
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User entered empty.	System	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 09:26:08
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Jessica Shaw(b) (4)	28 Jan 2021 16:56:25
DataPoint Un-verified.	Jessica Shaw (b) (4)	28 Jan 2021 16:56:20
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw(b) (4)	28 Jan 2021 16:56:20
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:34:17
DataPoint Verified.		03 Dec 2020 22:41:14
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Un-verified.	(b) (4) Jessica Shaw(b) (4)	28 Jan 2021 16:56:20
User entered '8 Jan 2021' reason for change: Data Entry Error	Jessica Shaw(b) (4)	28 Jan 2021 16:56:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:41:17
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:18
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User entered empty.	System	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:21
User entered 'No (N)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:40
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:42
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:44
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:46
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:48
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:51
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:52
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:54
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:57
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:41:59
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:01
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:03
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:04
User entered 'None (NONE)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:06
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:08
User entered 'l'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:10
User entered '0'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Un-verified.	(b) (4) Jessica Shaw(b) (4)	28 Jan 2021 16:56:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessica Shaw(b) (4)	28 Jan 2021 16:56:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:42:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:19
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:22
User entered empty.	Jessica Shaw(b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User entered '0'	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03
User entered 'I'	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:12:03

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:14:09
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'cause unknown per pt' (Site from DM).	Jessica Shaw(b) (4)	20 Jan 2021 22:54:36
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:34:41
User closed query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known.' (Site from DM).		22 Dec 2020 16:42:16
Query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known.' answered with 'midsternal chest pain ongoing in medical history, etiology unknown. captured worsening of ongoing medical history item.' (Site from DM).	Jessica Shaw(b) (4)	21 Dec 2020 22:07:18

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM, please update event term to reflect etiology/ medical diagnosis if known. (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:34:38
		03 Dec 2020 22:42:38
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: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:16:06
User coded data point as Term Coded data point by User (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:16:06
Data point term sent to Coder	System	23 Nov 2020 18:58:34
User entered 'worsening of midsternal chest pain'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:42
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:43
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:45
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:47
User entered '23 Oct 2020'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:48
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User entered empty.	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:50
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:52
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:42:53
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User entered empty.	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:40
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:42
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:46
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:48
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:50
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:51
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:53
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:55
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:57
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:43:59
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:02
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:05
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:08
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:10
User entered 'None (NONE)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:13
User entered 'l'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:15
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:17
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:31
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:44:33
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User entered '0'	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36
User entered 'I'	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 01:53:36

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
User closed query 'Per DM CLR: Please update the condition to confirm if the Lesion was benign or cancerous. Update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:14:40
Query 'Per DM CLR: Please update the condition to confirm if the Lesion was benign or cancerous. Update AE eCRF as appropriate. ' answered with 'unknown' (Site from DM).	Jessica Shaw (b) (4)	20 Jan 2021 22:54:59
User opened query 'Per DM CLR: Please update the condition to confirm if the Lesion was benign or cancerous. Update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	9 Jan 2021 03:35:12
DataPoint Verified.		3 Dec 2020 22:44:46
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Cyst of kidney - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:59:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:59:37
Data point term sent to Coder	System	23 Nov 2020 19:21:11
User entered 'cystic lesion within left kidney'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:48
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:50
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:20:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:20:54
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw(b) (4)	23 Nov 2020 19:20:54
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:20:49
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:52
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:54
User entered '23 Oct 2020'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:56
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:58
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:44:59
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:01
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:05
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:06
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:08
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:10
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:11
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:13
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4)	03 Dec 2020 22:45:23
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 22:45:22
DataPoint Verified.		03 Dec 2020 22:45:20
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:25
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:27
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:28
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:30
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:31
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:35
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:37
User entered 'None (NONE)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:39
User entered 'I'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:40
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:42
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:45
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:45:46
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:25:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:54:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Bilateral pleural effusion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 23:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 23:59:51
Data point term sent to Coder	System	08 Dec 2020 17:53:53
User entered 'bilateral pleural effusions'	Jessica Shaw (b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:55:20
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:55:27
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:55:37
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:55:43
User entered '06 Nov 2020'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:56:23
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User entered empty.	System	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:56:28
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:56:30
User entered '10 Nov 2020'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:56:34
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User entered empty.	System	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:56:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:56:44
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:56:57
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:58:01
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:58:03
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:58:04
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:58:09
User entered empty.	Jessica Shaw (b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:58:29
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:58:32
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:59:13
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:59:15
User entered '0'	Jessica Shaw (b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:59:17
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:59:19
User entered 'Not Related (NOT RELATED)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:59:27
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:59:31
User entered 'None (NONE)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen (b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:08
User entered 'l'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:10
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:12
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:25
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User signature succeeded.	Shane Christensen(b) (4)	13 Mar 2021 00:57:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:01:27
User entered 'incidental finding during hospitalization for pulmonary emboli.' reason for change: Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 17:53:56
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User entered '0'	System	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38
User entered 'I'	System	08 Dec 2020 17:53:38

US3282113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:11:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:25:43

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:05:49
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 06:25:57
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'updated' (Site from DM).	Jessica Shaw (b) (4)	23 Mar 2021 20:46:33
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:31:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:42
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:15:30

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:38
Data point term sent to Coder	System	23 Oct 2020 15:17:17
User entered 'atorvastatin'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hyperlipidemia'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '20'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2017'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:46:12
DataPoint Un-verified.	Jessica Shaw(b) (4)	06 Nov 2020 00:37:38
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw(b) (4)	06 Nov 2020 00:37:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:46:12
DataPoint Un-verified.	Jessica Shaw(b) (4)	06 Nov 2020 00:37:38
User entered '23 Oct 2020' reason for change: Data Entry Error	Jessica Shaw(b) (4)	06 Nov 2020 00:37:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User entered 'l'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User entered 'I'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:02
User entered '804 (804)'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:37
Data point term sent to Coder	System	23 Oct 2020 15:17:20
User entered 'levothyroxine'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hypothyroidism'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:36:31
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct' (Site from DM).	Jessica Shaw(b) (4)	08 Dec 2020 19:28:44
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:14:16
DataPoint Verified.		05 Nov 2020 21:38:19
User entered '85'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'ug (ug)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2017'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	04 Nov 2020 15:35:23
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '23 Oct 2020' reason for change: Data Entry Error	Jessica Shaw(b) (4)	04 Nov 2020 15:35:23
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User entered 'I'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User entered 'I'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:10
User entered '804 (804)'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:19:29
Data point term sent to Coder	System	23 Oct 2020 15:18:21
User entered 'tamsulosin'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'benign prostatic hyperplasia'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '.4'	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'twice daily (BID)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un Sep 2018'	Jessica Shaw(b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:23:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:23:42
Data point term sent to Coder	System	23 Oct 2020 15:18:22
User entered 'ipratropium bromide'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'seasonal allergies'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of number of sprays, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 11:36:47
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of number of sprays, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Jessica Shaw(b) (4)	08 Dec 2020 19:28:11
DataPoint Un-verified.	Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
User entered '34' reason for change: Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of number of sprays, 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)	08 Dec 2020 12:15:26
DataPoint Verified.		05 Nov 2020 21:38:19
User entered '2'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Un-verified.	(b) (4) Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
User entered 'ug (ug)' reason for change: Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Other (OTHER)'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
	(b) (4)	
DataPoint Un-verified.	Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
User entered empty; reason for change Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 19:28:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'sprays'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'as needed (PRN)'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2015'	Jessica Shaw(b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:43:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
Data point term sent to Coder	System	06 Nov 2020 00:48:01
Coding entries removed.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:15
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'corrected. added AE of CHF.' (Site from CRA).	Jessica Shaw (b) (4)	06 Nov 2020 00:47:07
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:39:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:04:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:04:26
Data point term sent to Coder	System	28 Oct 2020 14:44:33

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EAB) (1725)

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US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'losartan'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:43:09
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:15
User entered 'congestive heart failure' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:47:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '25'	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:46:39
DataPoint Un-verified.	dylan owen(b) (4)	19 Nov 2020 23:20:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) dylan owen(b) (4)	19 Nov 2020 23:20:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:46:39
DataPoint Un-verified.	dylan owen(b) (4)	19 Nov 2020 23:20:12
User entered '6 Nov 2020' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 23:20:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User entered 'I'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User entered 'I'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:48:02
User entered '804 (804)'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 00:48:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 00:48:31
Data point term sent to Coder	System	06 Nov 2020 00:48:01
Coding entries removed.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:04:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:04:44
Data point term sent to Coder	System	28 Oct 2020 14:44:35
User entered 'metoprolol'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:43:17
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).		16 Nov 2020 02:43:15
DataPoint Un-verified.	Jessica Shaw(b) (4)	06 Nov 2020 00:47:34
User entered 'congestive heart failure' reason for change: Data Entry Error	Jessica Shaw(b) (4)	06 Nov 2020 00:47:34
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'corrected. Added AE of CHF.' (Site from CRA).	Jessica Shaw(b) (4)	06 Nov 2020 00:47:26
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:39:38
DataPoint Verified.		05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '25'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import(b) (4)	06 Nov 2020 00:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import(b) (4)	06 Nov 2020 00:51:24
Data point term sent to Coder	System	06 Nov 2020 00:50:04
Coding entries removed.	Jessica Shaw(b) (4)	06 Nov 2020 00:49:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import(b) (4)	29 Oct 2020 17:46:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import(b) (4)	29 Oct 2020 17:46:37
Data point term sent to Coder	System	28 Oct 2020 14:45:36
User entered 'atorvastatin'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:43:26
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).		16 Nov 2020 02:43:24
DataPoint Un-verified.	Jessica Shaw(b) (4)	06 Nov 2020 00:49:18
User entered 'coronary artery disease' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:49:18
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'atorvastatin not given specifically for CHF. dosage was changed during hospital stay, for coronary artery disease diagnosis.' (Site from CRA).	Jessica Shaw(b) (4)	06 Nov 2020 00:49:11
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:40:15
DataPoint Verified.		05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '40'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:52:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:52:28
Data point term sent to Coder	System	04 Nov 2020 15:36:13
User entered 'levothyroxine'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hypothyroidism'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '88'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'ug (ug)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw(b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 12:14:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 12:14:59
Data point term sent to Coder	System	19 Nov 2020 00:08:30
User entered 'heparin'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'pulmonary thromboembolism'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'unk'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'Other (OTHER)'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'unknown'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'unknown (UNKNOWN)'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'Intravenous (INTRAVENOUS)'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'un Nov 2020'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered '0'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'No (N)'	Jessica Shaw(b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:11
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:28
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:59:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:59:53
Data point term sent to Coder	System	19 Nov 2020 00:09:30
User entered 'apixaban'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'pulmonary thromboembolism'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered '10'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'mg (mg)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'twice daily (BID)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'un Nov 2020'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered '0'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:02:16
DataPoint Un-verified.	Jessica Shaw (b) (4)	08 Dec 2020 18:43:52
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	08 Dec 2020 18:43:52
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:02:18
DataPoint Un-verified.	Jessica Shaw(b) (4)	08 Dec 2020 18:43:52
User entered '16 Nov 2020' reason for change: Data Entry Error	Jessica Shaw(b) (4)	08 Dec 2020 18:43:52
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:26
User entered 'No (N)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User entered '2'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User entered 'I'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:51
User entered '804 (804)'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import(b) (4) (b) (4)	19 Nov 2020 04:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import(b) (4) (b) (4)	19 Nov 2020 04:14:52
Data point term sent to Coder	System	19 Nov 2020 00:10:31
User entered 'aspirin'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'anti-coagulation post CABG'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered '81'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'mg (mg)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'once daily (QD)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered '0'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:47:41
User entered 'No (N)'	Jessica Shaw(b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:57
Data point term sent to Coder	System	19 Nov 2020 00:10:34
User entered 'oxycodone'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'No (N)'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'post CABG pain'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered '5'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'mg (mg)'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'as needed (PRN)'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'Oral (ORAL)'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered empty.	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'un Nov 2020'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered '0'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Nov 2020 18:59:41
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered '16 Nov 2020' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Nov 2020 18:59:41
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:47:55
User entered 'No (N)'	Jessica Shaw(b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:42
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.(9 days before dose 2).' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:32:25
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.(9 days before dose 2).' answered with 'deviation filed' (Site from DM).	Jessica Shaw(b) (4)	14 Dec 2020 16:47:12
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.(9 days before dose 2).' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 22:18:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 22:48:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\202003.	Coder Import(b) (4) (b) (4)	19 Nov 2020 23:37:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import(b) (4) (b) (4)	19 Nov 2020 23:37:51
Data point term sent to Coder	System	19 Nov 2020 23:23:24
Data point term sent to Coder	System	19 Nov 2020 23:22:24

PRODUCTION RELEASE (v12.003
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2081 of 2312

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Pneumovax'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'Yes (Y)'	dylan owen(b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'pneumonia phophylaxis'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'l'	dylan owen(b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'Other (OTHER)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'injection'	dylan owen(b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'once (ONCE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:22:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:22:45
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:22:21
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered '10 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered '0'	dylan owen(b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'No (N)'	dylan owen(b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered '10 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:11
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:08
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
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.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:07
Data point term sent to Coder	System	23 Nov 2020 19:26:20
User entered 'sodium chloride flush'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'coronary artery disease'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered '10'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'mL (mL)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'as needed (PRN)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'Intravenous (INTRAVENOUS)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:40
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:47:23
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
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, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:08
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:08
Data point term sent to Coder	System	23 Nov 2020 19:29:24
User entered 'sodium chloride 0.9% bolus'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'coronary artery disease'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered '333.55'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'mL (mL)'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'once (ONCE)'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered empty.	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered '23 Oct 2020'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered '0'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered '23 Oct 2020'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:48:57
User entered 'No (N)'	Jessica Shaw(b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:46:53
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:02:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import(b) (4) (b) (4)	08 Dec 2020 23:54:17
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 Dec 2020 23:54:17
Data point term sent to Coder	System	08 Dec 2020 18:45:01
User entered 'APIXABAN'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:02:47
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:03:21
User entered 'MULTIPLE SUBSEGMENTAL PULMONARY EMBOLI'	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:03:24
User entered '5'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:03:30
User entered 'mg (mg)'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:03:32
User entered empty.	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:02
User entered 'twice daily (BID)'	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:04
User entered empty.	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:06
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:08
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:11
User entered '17 Nov 2020'	Jessica Shaw (b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:14
User entered '0'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:16
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
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).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 09:26:40
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 'pt continues to take medication, per physician orders, even though AE is resolved.' (Site from DM).	Jessica Shaw(b) (4)	28 Jan 2021 16:59:01
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)	25 Jan 2021 04:53:17
DataPoint Verified.		06 Jan 2021 22:04:19
User entered empty.	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 22:04:23
User entered 'No (N)'	Jessica Shaw(b) (4)	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 18:44:24

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:25:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:05:49
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 22:49:04
User entered 'Yes (Y)'	Jessica Shaw(b) (4)	04 Nov 2020 19:37:07

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:49:10
User entered '2 Nov 2020'	Jessica Shaw(b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:49:10
User entered 'coronary artery bypass graft'	Jessica Shaw(b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:49:10
User entered 'Adverse Event (AE)'	Jessica Shaw(b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:49:10
User entered empty.	Jessica Shaw(b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:29
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered '30 Oct 2020'	(b) (4) Jessica Shaw(b) (4)	22 Jan 2021 17:30:48

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:29
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'EKG'	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:30:48

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:29
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Adverse Event (AE)'	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:30:48

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:29
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered empty.	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:30:48

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:32
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '23 Oct 2020'	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:31:18

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:32
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 17:31:28
User entered 'CT CORONAY ANGIOGRAPHY' reason for change: Data Entry Error	System	22 Jan 2021 17:31:28
User opened query 'Data is required. Please complete.' (Site from System).	Jessica Shaw (b) (4)	22 Jan 2021 17:31:28
User entered empty.	Jessica Shaw (b) (4)	22 Jan 2021 17:31:18

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:32
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered 'Adverse Event (AE)'	(b) (4) Jessica Shaw(b) (4)	22 Jan 2021 17:31:18

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:32
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered empty.	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:31:18

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:38
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered '27 Oct 2020'	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:31:47

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:38
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered 'cardiac catheterization'	(b) (4) Jessica Shaw(b) (4)	22 Jan 2021 17:31:47

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:38
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
User entered 'Adverse Event (AE)'	(b) (4) Jessica Shaw (b) (4)	22 Jan 2021 17:31:47

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:47:38
User signature succeeded.	Shane Christensen(b) (4)	01 Apr 2021 19:09:47
User entered empty.	(b) (4) Jessica Shaw(b) (4)	22 Jan 2021 17:31:47

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen(b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered '28/Oct/2020 16:23'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

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)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'l'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:36:30
User entered '05/Nov/2020 14:28'	System	05 Nov 2020 14:28:38

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:05:12
DataPoint Verified.		05 Nov 2020 21:36:30
User entered 'l'		05 Nov 2020 14:28:38

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:37:56
User entered '17/Nov/2020 19:05'	System	17 Nov 2020 19:05:23

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:21:10
DataPoint Verified.		03 Dec 2020 22:37:56
User entered 'I'		17 Nov 2020 19:05:23

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	03 Dec 2020 22:37:58
User entered '24/Nov/2020 11:31'	System	24 Nov 2020 16:31:36

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 16:21:10
DataPoint Verified.		03 Dec 2020 22:37:58
User entered 'l'		24 Nov 2020 16:31:36

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:49:15
User entered '05/Dec/2020 16:21'	System	05 Dec 2020 16:21:20

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4)	06 Jan 2021 21:49:15
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 14:22:37
User entered 'l'		05 Dec 2020 16:21:20

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'		28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.		05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:49:19
User entered '09/Dec/2020 14:23'	System	09 Dec 2020 14:23:02

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4)	06 Jan 2021 21:49:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 15:39:24
User entered 'l'		09 Dec 2020 14:23:02

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	5 Nov 2020 21:36:30
Reviewed for Safety.		5 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	28 Dec 2020 15:39:39
User entered '6'	System	09 Dec 2020 14:23:02
User entered '5'	System	05 Dec 2020 16:21:20
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	06 Jan 2021 21:49:22
User entered '28/Dec/2020 10:39'	System	28 Dec 2020 15:39:39

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:25:43

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.	Shane Christensen (b) (4)	01 Apr 2021 19:09:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:49:22
User entered 'I'		28 Dec 2020 15:39:39