

US3912113 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:48:45

All time stamps listed in this document are displayed in GMT

US3912113

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

[Participant ID](#)

US3912113

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

US3912113

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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

Visit date (dd MMM yyyy)	04 SEP 2020
--------------------------	-------------

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

Folder OID	SCRN
------------	------

US3912113

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
Sex	Female <input checked="" type="radio"/> Male <input 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

US3912113

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3912113

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Were any significant conditions reported?

Yes ☒

No ☐

US3912113

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

US3912113

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Condition	ASTHMA (MILD)
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3912113

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Condition	WEIGHT LOSS
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912113

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Condition	NAUSEA
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912113

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:03 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:03
Height (<i>xxx.x</i>)	65.5 in
Weight (<i>xxx.x</i>)	109 lb
BMI (<i>xxx.x</i>)	17.90003 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912113

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3912113

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Date of assessment (dd MMM yyyy) 04 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3912113

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 04 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3912113

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3912113

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3912113

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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

What was the participant's randomization number? 111489

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 ☒

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Height	ND - Not Done
Weight	ND - Not Done

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:03 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:03
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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)	04 SEP 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 16:14
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3912113

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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.

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:36 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:36

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

US3912113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

14:53 (24 HR)

Collection date and time (derived)

04 SEP 2020 14:53

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:57	04 SEP 2020 14:57
Nasopharyngeal Swab 2	No		

US3912113

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

98.0 °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

04 SEP 2020 16:35

PC Open Date & Time

04 SEP 2020 15:56

PC Close Date & Time

04 SEP 2020 18:26

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	04 SEP 2020 21:10
PC Open Date & Time	04 SEP 2020 19:21
PC Close Date & Time	05 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 17:18

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

98.0 °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

07 SEP 2020 17:43

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

97.5 °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

08 SEP 2020 19:16

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

98.6 °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

09 SEP 2020 18:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

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

10 SEP 2020 22:10

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

04 SEP 2020 16:36

PC Open Date & Time

04 SEP 2020 15:56

PC Close Date & Time

04 SEP 2020 18:26

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

04 SEP 2020 21:12

PC Open Date & Time

04 SEP 2020 19:21

PC Close Date & Time

05 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:18

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 16:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:16

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	10 SEP 2020 22:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 16:36
PC Open Date & Time	04 SEP 2020 15:56
PC Close Date & Time	04 SEP 2020 18:26

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:13
PC Open Date & Time	04 SEP 2020 19:21
PC Close Date & Time	05 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

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 ☒

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:19
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

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 1744

EAB) (1725)

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:17
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

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 1744

EAB) (1725)

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

54 of 1744

EAB) (1725)

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:16
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

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 1744

EAB) (1725)

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:22
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

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 ☒

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 22:11
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3912113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT2

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

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)	02 OCT 2020
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:17
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

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)	02 OCT 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 15:15
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3912113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 02 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 14:44 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 14:44

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

US3912113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

13:56 (24 HR)

Collection date and time (derived)

2 OCT 2020 13:56

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:01	2 OCT 2020 14:01
Nasopharyngeal Swab 2	No		

US3912113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 15:16

PC Open Date & Time

02 OCT 2020 15:04

PC Close Date & Time

02 OCT 2020 17:34

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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 98.6 °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	02 OCT 2020 20:12
PC Open Date & Time	02 OCT 2020 18:29
PC Close Date & Time	03 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 12:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	04 OCT 2020 19:36
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

99.5 °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

05 OCT 2020 17:22

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

06 OCT 2020 15:07

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

98.6 °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

07 OCT 2020 20:16

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

98.4 °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

09 OCT 2020 00:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

02 OCT 2020 15:16

PC Open Date & Time

02 OCT 2020 15:04

PC Close Date & Time

02 OCT 2020 17:34

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

02 OCT 2020 20:13

PC Open Date & Time

02 OCT 2020 18:29

PC Close Date & Time

03 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

03 OCT 2020 12:59

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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 ☐

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

40

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 19:36

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

05 OCT 2020 17:22

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

06 OCT 2020 15:07

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

07 OCT 2020 20:16

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

09 OCT 2020 00:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 15:17
PC Open Date & Time	02 OCT 2020 15:04
PC Close Date & Time	02 OCT 2020 17:34

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 20:14
PC Open Date & Time	02 OCT 2020 18:29
PC Close Date & Time	03 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

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 ☒

PRODUCTION RELEASE (v12.003

95 of 1744

EAB) (1725)

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

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 ☒

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:37
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

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 ☒

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:22
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

101 of 1744

EAB) (1725)

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 15:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

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 ☒

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 20:17
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

105 of 1744

EAB) (1725)

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 00:25
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 10 OCT 2020 16:23

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 16:23
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3912113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 13:37
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

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.

US3912113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

13:52 (24 HR)

Collection date and time (derived)

30 OCT 2020 13:52

US3912113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 71

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

No ☒

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

11 NOV 2020 15:38:36

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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

22 NOV 2020 00:13:07

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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

29 NOV 2020 00:12:35

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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	08 DEC 2020 18:50:01
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

13 DEC 2020 09:55:53

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 00:02:26
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

27 DEC 2020 00:02:20

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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	03 JAN 2021 00:36:55
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 JAN 2021 00:30:13
Patient Cloud Open Date & Time	10 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	134 of 1744

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

17 JAN 2021 12:59:39

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

24 JAN 2021 18:34:26

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:28:00

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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	07 FEB 2021 00:40:46
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

14 FEB 2021 00:13:08

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

22 FEB 2021 10:38:31

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 MAR 2021 23:19:18
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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 MAR 2021 11:02:31

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 10:08:57

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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

05 APR 2021 15:23:11

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 15:24:24

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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

18 APR 2021 00:05:45

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☒

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 10:53:45

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 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"/>
Date and time of submission	02 MAY 2021 22:51:33
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐
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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

Patient Cloud Open Date & Time	22 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	26 AUG 2021 23:59
---	-------------------

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐
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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 453

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

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

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

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

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

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

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 551

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

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

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

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

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

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

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐
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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐
Yes ☐

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 712

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

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

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

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

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

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

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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ 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 ☐

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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"/>

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3912113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:48:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 23:19:52

US3912113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 20:32:22

Generated On: 12 Aug 2021 13:48:45

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

Visit date (dd MMM yyyy)	13 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 20:32:22

Generated On: 12 Aug 2021 13:48:45

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3912113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 20:32:22

Generated On: 12 Aug 2021 13:48:45

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.

US3912113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 20:32:22

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 APR 2021

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

13 APR 2021 14:58

US3912113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 20:32:22

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912113

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3912113

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:48:45

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"/>

US3912113

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:48:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3912113

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

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

Visit date (dd MMM yyyy)	3 MAR 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3912113

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

Date of updated informed consent (dd MMM yyyy) 3 MAR 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) 3 MAR 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 _____

US3912113

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

12:49 (24 HR)

Collection date and time (derived)

3 MAR 2021 12:49

US3912113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00 - 23:59)	12:54
Collection Date and Time (derived)	3 MAR 2021 12:54

US3912113

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 17:50:52

Generated On: 12 Aug 2021 13:48:45

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 19:56:07

Generated On: 12 Aug 2021 13:48:45

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

Yes ☒

No ☐

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

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

Name of Medication KLONOPIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 1744

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

	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 MAY 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 1744

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	UN UNK 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

Name of Medication TYLENOL, EXTRA STRENGTH,
500 MG TABS

Prophylaxis Yes ☐
No ☒

Indication PAIN AT THE INJECTION SITE

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 1744

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

	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)	03 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 checked="" type="radio"/>
	No	<input type="radio"/>
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"/>

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:21:20

Generated On: 12 Aug 2021 13:48:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 16:20:37

Generated On: 12 Aug 2021 13:48:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
6 OCT 2020	UPPER LOWER ENDOSCOPY	Medical History	

US3912113

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:48:45

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 ☐

Audit

US3912113 (Prod: Synexus - Optimal Research - Austin)

US3912113

Form: Participant Creation

Generated On: 12 Aug 2021 13:48:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:04:50
User entered 'US3912113'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:39:37

US3912113

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:08:54
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:03

US3912113

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:08:54
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:39:38

US3912113

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:08:54
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:03

US3912113

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'SCRN'	System	04 Sep 2020 20:35:03

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered (b) (6) 1988'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:39:39

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '32'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'YEARS'	System	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '32'	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered 'Female (F)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered 'I'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:48:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:40:43

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered '4 Sep 2020'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'Sep 2020'	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '2020'	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered 'Amendment 3 (3)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	08 Sep 2020 00:01:46
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:29
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	08 Sep 2020 00:01:46
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	04 Sep 2020 20:41:28
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:39:38

US3912113

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:48:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'I'	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:09:38
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:19

US3912113

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:48:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:22
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:42:33

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:03:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:03:36
Data point term sent to Coder	System	08 Sep 2020 00:02:40
User entered 'Anxiety'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered 'un UNK 2003'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'Jan 2003'	System	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '2003'	System	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	08 Sep 2020 00:02:27

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 12:48:46
User closed query 'Please clarify whether subject has mild, moderate or severe asthma. Thank you!' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 14:10:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:11:41
Data point term sent to Coder	System	25 Sep 2020 12:10:42
Query 'Please clarify whether subject has mild, moderate or severe asthma. Thank you!' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 12:10:14
DataPoint Un-verified.	(b) (4), (b) (6)	25 Sep 2020 12:10:10
Coding entries removed.	(b) (4), (b) (6)	25 Sep 2020 12:10:10
User entered 'ASTHMA (mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 12:10:10
User opened query 'Please clarify whether subject has mild, moderate or severe asthma. Thank you!' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 20:35:42
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:04:37
Data point term sent to Coder	System	08 Sep 2020 00:03:40

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 1744

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

[Condition](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered 'un UNK 2001'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:49:33
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:11:33
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'Jan 2001'	System	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '2001'	System	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	08 Sep 2020 00:02:43

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User coded data point as SOC: Investigations, HLGT: Physical examination and organ system status topics, HLT: Physical examination procedures and organ system status, PT: Weight decreased, LLT: Weight loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 06:43:19
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 06:43:19
Data point term sent to Coder	System	16 Oct 2020 18:23:35
User entered 'weight loss'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User entered 'un Mar 2020'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User entered '0'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User entered empty.	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:43
User entered '0'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'Mar 2020'	System	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '2020'	System	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	16 Oct 2020 18:22:49

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 06:43:09
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 06:43:09
Data point term sent to Coder	System	16 Oct 2020 18:23:41
User entered 'nausea'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User entered 'un Mar 2020'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User entered '0'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User entered empty.	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:49:48
User entered '0'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'Mar 2020'	System	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '2020'	System	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	16 Oct 2020 18:23:15

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:49
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:47
User entered '14:03'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '04 Sep 2020 14:03'	System	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:51
User entered '65.5' in	Tina Rountree (b) (4)	08 Sep 2020 00:03:55
DataPoint set to visible.	(b) (4) System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:53
User entered '109' lb	Tina Rountree (b) (4)	08 Sep 2020 00:03:55
DataPoint set to visible.	(b) (4) System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered '17.90003'	System	08 Sep 2020 00:03:55
DataPoint set to visible.	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'kg/m2'	System	08 Sep 2020 00:03:55
DataPoint set to visible.	System	04 Sep 2020 20:41:28

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'bpm'	System	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'breaths/min'	System	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'mmHg'	System	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:11:56
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered 'mmHg'	System	08 Sep 2020 00:03:55

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07

US3912113

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07

(

US3912113

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:06
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:08

US3912113

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:06
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:23
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:23
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:23
User entered '04 Sep 2020' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:08
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	08 Sep 2020 00:04:08
User entered '03 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:08

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:48:45

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:24
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:04:58

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered '04 Sep 2020'	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered 'Urine (URINE)'	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered 'Negative (NEGATIVE)'	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered empty.	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:50:20
User entered empty.	Amy Collins (b) (4) (b) (4)	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User entered empty.	System	22 Sep 2020 13:10:35

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
User entered '0'	Tina Rountree (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered 'I'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
User entered '0'	Tina Rountree (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:48:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:23:58
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:05:28

US3912113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:24:17
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:33

US3912113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:24:17
User entered '4 Sep 2020'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:33

US3912113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:24:17
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:35:33

US3912113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'VISIT1'	System	04 Sep 2020 20:35:33

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:43

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered '111489'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:43

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:43

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:18:27

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:18:27

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:18:27

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:18:27

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:18:27

US3912113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:51:28
User entered 'No (N)'	Amy Collins (b) (4)	22 Sep 2020 13:10:57
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:28:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:28:19

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:14
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:14
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:58
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:57
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:55
User entered '14:03'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '04 Sep 2020 14:03'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:12:53
User entered '36.7' C	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:00
User entered 'Oral (Oral)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:03
User entered '77'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'bpm'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:05
User entered '14'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'breaths/min'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:07
User entered '101'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
User closed query 'Previous query response indicates, "data correct", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 08:22:57
Query 'Previous query response indicates, "data correct", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' answered with 'Data confirmed. NCS per PI' (Site from DM).	Tina Rountree (b) (4) (b) (4)	05 Oct 2020 23:19:22
User opened query 'Previous query response indicates, "data correct", however it was not indicated whether this was CS/NCS. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:39:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 13:39:36
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'data correct.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 13:54:47
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:00
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:13:08
User entered '58'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:14
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:48:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:13:13
User entered missing code ND - Not Done.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:38:46
User entered '16:14'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '04 Sep 2020 16:14'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:38:48
User entered '36.7' C	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:38:51
User entered 'Oral (Oral)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:38:52
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered '82'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'bpm'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered '14'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'breaths/min'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered '115'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:01
User entered '79'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	08 Sep 2020 00:07:53

US3912113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:36:01
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:59

US3912113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:36:01
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:07:59

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
User closed query 'Per CDM: As per CCGs pages 15-16, please record this as NO and remove date for Pregnancy Test and PE forms at V1 Day 1. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:24:54
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:17:26
Query 'Per CDM: As per CCGs pages 15-16, please record this as NO and remove date for Pregnancy Test and PE forms at V1 Day 1. Thank you. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:52:36
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 13:52:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:52:31
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:35:54
User opened query 'Per CDM: As per CCGs pages 15-16, please record this as NO and remove date for Pregnancy Test and PE forms at V1 Day 1. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 09:56:29
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 13:52:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:52:31
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 13:52:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:52:31
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered 'Urine (URINE)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 13:52:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:52:31
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered 'Negative (NEGATIVE)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:40:16
User closed query 'PER CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the Pregnancy form is only required to be completed using the Pregnancy form located in the screening folder. Completion of the Pregnancy form within the Visit 1 Day 1 folder should be left blank except for the response to Was the pregnancy test performed? And Was FSH sample collected? Both should be 'NO'. Please update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:15:46
Query 'PER CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the Pregnancy form is only required to be completed using the Pregnancy form located in the screening folder. Completion of the Pregnancy form within the Visit 1 Day 1 folder should be left blank except for the response to Was the pregnancy test performed? And Was FSH sample collected? Both should be 'NO'. Please update accordingly. Thank you. ' answered with 'corrected' (Site from DM).	Tina Rountree (b) (4) (b) (4)	05 Oct 2020 12:57:14
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	05 Oct 2020 12:57:03
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	05 Oct 2020 12:57:03

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User opened query 'PER CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the Pregnancy form is only required to be completed using the Pregnancy form located in the screening folder. Completion of the Pregnancy form within the Visit 1 Day 1 folder should be left blank except for the response to Was the pregnancy test performed? And Was FSH sample collected? Both should be 'NO'. Please update accordingly. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 04:11:05
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 19:17:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 13:52:31
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered 'No (N)'	Tina Rountree (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:35:54
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered empty.	System	08 Sep 2020 00:08:14

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered '4 Sep 2020'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered '15:36'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '4 Sep 2020 15:36'	System	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:31:47
User entered 'ONCE'	System	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:44:02

US3912113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:47
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:41

US3912113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:47
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:41

US3912113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:47
User entered '14:53'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:08:41

US3912113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '04 Sep 2020 14:53'	System	08 Sep 2020 00:08:41

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:34
User entered '04 Sep 2020'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:34
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:34
User entered '14:57'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '04 Sep 2020 14:57'	System	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:34
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:26:34
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered empty.	System	08 Sep 2020 00:09:01

US3912113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:39:16
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:06

US3912113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '1'	System	08 Sep 2020 00:09:06

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:12', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ba1db68a-0b7a-4f98-95b2-8b0cf579dc1d'	System	04 Sep 2020 21:36:58
User entered 'Yes (Y)'	System	04 Sep 2020 21:36:58

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:20', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ba1db68a-0b7a-4f98-95b2-8b0cf579dc1d'	System	04 Sep 2020 21:36:58
User entered '98.0'	System	04 Sep 2020 21:36:58

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ba1db68a-0b7a-4f98-95b2-8b0cf579dc1d'	System	04 Sep 2020 21:36:58
User entered 'No (N)'	System	04 Sep 2020 21:36:58

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ba1db68a-0b7a-4f98-95b2-8b0cf579dc1d'	System	04 Sep 2020 21:36:58
User entered '04 Sep 2020 16:35'	System	04 Sep 2020 21:36:58

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 15:56'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 18:26'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:10:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '91b55507-2454-4f48-ad16-116b45211779'	System	05 Sep 2020 02:12:24
User entered 'Yes (Y)'	System	05 Sep 2020 02:12:24

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:10:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '91b55507-2454-4f48-ad16-116b45211779'	System	05 Sep 2020 02:12:24
User entered '97.6'	System	05 Sep 2020 02:12:24

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:10:51', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '91b55507-2454-4f48-ad16-116b45211779'	System	05 Sep 2020 02:12:24
User entered 'No (N)'	System	05 Sep 2020 02:12:24

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:10:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '91b55507-2454-4f48-ad16-116b45211779'	System	05 Sep 2020 02:12:24
User entered '04 Sep 2020 21:10'	System	05 Sep 2020 02:12:24

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 19:21'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 2'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c8fa5199-988b-436d-9669-53d35bca60ca'	System	05 Sep 2020 22:19:50
User entered 'Yes (Y)'	System	05 Sep 2020 22:19:50

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c8fa5199-988b-436d-9669-53d35bca60ca'	System	05 Sep 2020 22:19:50
User entered '98.4'	System	05 Sep 2020 22:19:50

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:18', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c8fa5199-988b-436d-9669-53d35bca60ca'	System	05 Sep 2020 22:19:50
User entered 'No (N)'	System	05 Sep 2020 22:19:50

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c8fa5199-988b-436d-9669-53d35bca60ca'	System	05 Sep 2020 22:19:50
User entered '05 Sep 2020 17:18'	System	05 Sep 2020 22:19:50

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 3'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:19:28', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7a9ae781-5907-41c6-91a3-468beb7b66b9'	System	06 Sep 2020 21:21:14
User entered 'Yes (Y)'	System	06 Sep 2020 21:21:14

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:19:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7a9ae781-5907-41c6-91a3-468beb7b66b9' User entered '98.8'	System	06 Sep 2020 21:21:14
	System	06 Sep 2020 21:21:14

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:19:38', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7a9ae781-5907-41c6-91a3-468beb7b66b9'	System	06 Sep 2020 21:21:14
User entered 'No (N)'	System	06 Sep 2020 21:21:14

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:19:47', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7a9ae781-5907-41c6-91a3-468beb7b66b9'	System	06 Sep 2020 21:21:14
User entered '06 Sep 2020 16:19'	System	06 Sep 2020 21:21:14

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 4'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4c089cb0-b6f5-45c6-a155-591931dc76ee'	System	07 Sep 2020 22:45:08
User entered 'Yes (Y)'	System	07 Sep 2020 22:45:08

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4c089cb0-b6f5-45c6-a155-591931dc76ee'	System	07 Sep 2020 22:45:08
User entered '98.0'	System	07 Sep 2020 22:45:08

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:32', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4c089cb0-b6f5-45c6-a155-591931dc76ee'	System	07 Sep 2020 22:45:08
User entered 'No (N)'	System	07 Sep 2020 22:45:08

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:41', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4c089cb0-b6f5-45c6-a155-591931dc76ee'	System	07 Sep 2020 22:45:08
User entered '07 Sep 2020 17:43'	System	07 Sep 2020 22:45:08

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 5'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:15:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '10359e3b-9181-495d-9354-d299860d9729'	System	09 Sep 2020 00:17:26
User entered 'Yes (Y)'	System	09 Sep 2020 00:17:26

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:15:57', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '10359e3b-9181-495d-9354-d299860d9729'	System	09 Sep 2020 00:17:26
User entered '97.5'	System	09 Sep 2020 00:17:26

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:15:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '10359e3b-9181-495d-9354-d299860d9729'	System	09 Sep 2020 00:17:26
User entered 'No (N)'	System	09 Sep 2020 00:17:26

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:02', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '10359e3b-9181-495d-9354-d299860d9729'	System	09 Sep 2020 00:17:26
User entered '08 Sep 2020 19:16'	System	09 Sep 2020 00:17:26

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 6'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f9350f15-fefc-40e2-a22f-80d6ce811726'	System	09 Sep 2020 23:23:40
User entered 'Yes (Y)'	System	09 Sep 2020 23:23:40

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f9350f15-fefc-40e2-a22f-80d6ce811726'	System	09 Sep 2020 23:23:40
User entered '98.6'	System	09 Sep 2020 23:23:40

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f9350f15-fefc-40e2-a22f-80d6ce811726'	System	09 Sep 2020 23:23:40
User entered 'No (N)'	System	09 Sep 2020 23:23:40

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:16', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f9350f15-fefc-40e2-a22f-80d6ce811726'	System	09 Sep 2020 23:23:40
User entered '09 Sep 2020 18:22'	System	09 Sep 2020 23:23:40

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 7'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6a807d41-61b9-45cd-af13-6b84d6818292'	System	11 Sep 2020 03:12:12
User entered 'Yes (Y)'	System	11 Sep 2020 03:12:12

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:34', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6a807d41-61b9-45cd-af13-6b84d6818292'	System	11 Sep 2020 03:12:12
User entered '98.2'	System	11 Sep 2020 03:12:12

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:44', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6a807d41-61b9-45cd-af13-6b84d6818292'	System	11 Sep 2020 03:12:12
User entered 'No (N)'	System	11 Sep 2020 03:12:12

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:47', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6a807d41-61b9-45cd-af13-6b84d6818292'	System	11 Sep 2020 03:12:12
User entered '10 Sep 2020 22:10'	System	11 Sep 2020 03:12:12

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a2bcfd3a-a2fa-4c07-a4c0-3699f7e00efe'	System	04 Sep 2020 21:37:35
User entered 'None (1)'	System	04 Sep 2020 21:37:35

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a2bcfd3a-a2fa-4c07-a4c0-3699f7e00efe'	System	04 Sep 2020 21:37:35
User entered 'No (N)'	System	04 Sep 2020 21:37:35

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:35:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a2bcfd3a-a2fa-4c07-a4c0-3699f7e00efe'	System	04 Sep 2020 21:37:35
User entered 'No (N)'	System	04 Sep 2020 21:37:35

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a2bcfd3a-a2fa-4c07-a4c0-3699f7e00efe'	System	04 Sep 2020 21:37:35
User entered 'None (1)'	System	04 Sep 2020 21:37:35

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a2bcfd3a-a2fa-4c07-a4c0-3699f7e00efe'	System	04 Sep 2020 21:37:35
User entered '04 Sep 2020 16:36'	System	04 Sep 2020 21:37:35

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 15:56'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 18:26'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:11:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'fb7f7d97-7731-4d93-b01f-0e9c75a26187'	System	05 Sep 2020 02:14:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Sep 2020 02:14:09

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:11:45', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'fb7f7d97-7731-4d93-b01f-0e9c75a26187'	System	05 Sep 2020 02:14:09
User entered 'No (N)'	System	05 Sep 2020 02:14:09

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'fb7f7d97-7731-4d93-b01f-0e9c75a26187'	System	05 Sep 2020 02:14:09
User entered 'No (N)'	System	05 Sep 2020 02:14:09

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:40', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'fb7f7d97-7731-4d93-b01f-0e9c75a26187'	System	05 Sep 2020 02:14:09
User entered 'None (1)'	System	05 Sep 2020 02:14:09

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:44', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'fb7f7d97-7731-4d93-b01f-0e9c75a26187'	System	05 Sep 2020 02:14:09
User entered '04 Sep 2020 21:12'	System	05 Sep 2020 02:14:09

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 19:21'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 2'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:32', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2dc0e448-563c-479f-a25e-b7c9e5a4a67f'	System	05 Sep 2020 22:20:15
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 22:20:15

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2dc0e448-563c-479f-a25e-b7c9e5a4a67f'	System	05 Sep 2020 22:20:15
User entered 'No (N)'	System	05 Sep 2020 22:20:15

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2dc0e448-563c-479f-a25e-b7c9e5a4a67f'	System	05 Sep 2020 22:20:15
User entered 'No (N)'	System	05 Sep 2020 22:20:15

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:45', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2dc0e448-563c-479f-a25e-b7c9e5a4a67f'	System	05 Sep 2020 22:20:15
User entered 'None (1)'	System	05 Sep 2020 22:20:15

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2dc0e448-563c-479f-a25e-b7c9e5a4a67f'	System	05 Sep 2020 22:20:15
User entered '05 Sep 2020 17:18'	System	05 Sep 2020 22:20:15

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 3'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f3f82dc5-bdd3-45cb-8413-cd8e871b9bc0'	System	06 Sep 2020 21:18:45
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 21:18:45

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:08', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f3f82dc5-bdd3-45cb-8413-cd8e871b9bc0'	System	06 Sep 2020 21:18:45
User entered 'No (N)'	System	06 Sep 2020 21:18:45

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:10', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f3f82dc5-bdd3-45cb-8413-cd8e871b9bc0'	System	06 Sep 2020 21:18:45
User entered 'No (N)'	System	06 Sep 2020 21:18:45

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f3f82dc5-bdd3-45cb-8413-cd8e871b9bc0'	System	06 Sep 2020 21:18:45
User entered 'None (1)'	System	06 Sep 2020 21:18:45

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:18', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'f3f82dc5-bdd3-45cb-8413-cd8e871b9bc0'	System	06 Sep 2020 21:18:45
User entered '06 Sep 2020 16:17'	System	06 Sep 2020 21:18:45

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 4'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '98569847-5a0b-48fc-87da-f84580a47bbf'	System	07 Sep 2020 22:46:06
User entered 'None (1)'	System	07 Sep 2020 22:46:06

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '98569847-5a0b-48fc-87da-f84580a47bbf'	System	07 Sep 2020 22:46:06
User entered 'No (N)'	System	07 Sep 2020 22:46:06

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:43:57', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '98569847-5a0b-48fc-87da-f84580a47bbf'	System	07 Sep 2020 22:46:06
User entered 'No (N)'	System	07 Sep 2020 22:46:06

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:44:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '98569847-5a0b-48fc-87da-f84580a47bbf'	System	07 Sep 2020 22:46:06
User entered 'None (1)'	System	07 Sep 2020 22:46:06

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:44:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '98569847-5a0b-48fc-87da-f84580a47bbf'	System	07 Sep 2020 22:46:06
User entered '07 Sep 2020 17:44'	System	07 Sep 2020 22:46:06

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 5'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2154ea7d-6b30-409d-b3a0-2ec8703d276c'	System	09 Sep 2020 00:17:38
User entered 'None (1)'	System	09 Sep 2020 00:17:38

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2154ea7d-6b30-409d-b3a0-2ec8703d276c'	System	09 Sep 2020 00:17:38
User entered 'No (N)'	System	09 Sep 2020 00:17:38

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2154ea7d-6b30-409d-b3a0-2ec8703d276c'	System	09 Sep 2020 00:17:38
User entered 'No (N)'	System	09 Sep 2020 00:17:38

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2154ea7d-6b30-409d-b3a0-2ec8703d276c'	System	09 Sep 2020 00:17:38
User entered 'None (1)'	System	09 Sep 2020 00:17:38

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2154ea7d-6b30-409d-b3a0-2ec8703d276c'	System	09 Sep 2020 00:17:38
User entered '08 Sep 2020 19:16'	System	09 Sep 2020 00:17:38

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 6'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '451ec2fb-821a-4b8a-8d7d-2f7585726a2c'	System	09 Sep 2020 23:23:52
User entered 'None (1)'	System	09 Sep 2020 23:23:52

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '451ec2fb-821a-4b8a-8d7d-2f7585726a2c'	System	09 Sep 2020 23:23:52
User entered 'No (N)'	System	09 Sep 2020 23:23:52

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:23', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '451ec2fb-821a-4b8a-8d7d-2f7585726a2c'	System	09 Sep 2020 23:23:52
User entered 'No (N)'	System	09 Sep 2020 23:23:52

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '451ec2fb-821a-4b8a-8d7d-2f7585726a2c'	System	09 Sep 2020 23:23:52
User entered 'None (1)'	System	09 Sep 2020 23:23:52

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:28', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '451ec2fb-821a-4b8a-8d7d-2f7585726a2c'	System	09 Sep 2020 23:23:52
User entered '09 Sep 2020 18:22'	System	09 Sep 2020 23:23:52

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 7'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2a4ed94b-3382-402c-b0eb-fa048e62cae2'	System	11 Sep 2020 03:12:31
User entered 'None (1)'	System	11 Sep 2020 03:12:31

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2a4ed94b-3382-402c-b0eb-fa048e62cae2'	System	11 Sep 2020 03:12:31
User entered 'No (N)'	System	11 Sep 2020 03:12:31

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:10:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2a4ed94b-3382-402c-b0eb-fa048e62cae2'	System	11 Sep 2020 03:12:31
User entered 'No (N)'	System	11 Sep 2020 03:12:31

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2a4ed94b-3382-402c-b0eb-fa048e62cae2'	System	11 Sep 2020 03:12:31
User entered 'None (1)'	System	11 Sep 2020 03:12:31

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2a4ed94b-3382-402c-b0eb-fa048e62cae2'	System	11 Sep 2020 03:12:31
User entered '10 Sep 2020 22:11'	System	11 Sep 2020 03:12:31

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:12', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:18', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:20', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:25', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'None (0)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered 'No (N)'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T16:36:31', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd4886cf9-a5cd-4291-91d2-acb0793d7287'	System	04 Sep 2020 21:37:58
User entered '04 Sep 2020 16:36'	System	04 Sep 2020 21:37:58

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 15:56'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 18:26'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:51', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:57', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:12:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'None (0)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:13:02', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered 'No (N)'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-04T21:13:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '052cff09-0ce3-492b-8a30-f9b92e1a8350'	System	05 Sep 2020 02:14:33
User entered '04 Sep 2020 21:13'	System	05 Sep 2020 02:14:33

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Sep 2020 19:21'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 2'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:57', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:18:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:19:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:19:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'None (0)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:19:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered 'No (N)'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-05T17:19:06', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bb14f45b-9952-4091-b751-245c7eaf7814'	System	05 Sep 2020 22:20:37
User entered '05 Sep 2020 17:19'	System	05 Sep 2020 22:20:37

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 3'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:27', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'None (0)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:32', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered 'No (N)'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-06T16:17:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '384e2c95-6782-4dfd-8196-b49dde33805c'	System	06 Sep 2020 21:19:02
User entered '06 Sep 2020 16:17'	System	06 Sep 2020 21:19:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 4'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:20', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:23', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:38', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:49', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:51', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'None (0)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered 'No (N)'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-07T17:45:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c66efb2-89cd-4d0a-8742-4e100aef9549'	System	07 Sep 2020 22:47:23
User entered '07 Sep 2020 17:45'	System	07 Sep 2020 22:47:23

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 5'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:28', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'None (0)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:33', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered 'No (N)'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-08T19:16:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '6797ac52-db7a-4509-b131-4c018f941509'	System	09 Sep 2020 00:18:00
User entered '08 Sep 2020 19:16'	System	09 Sep 2020 00:18:00

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 6'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:31', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:32', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:34', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:38', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'None (0)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered 'No (N)'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-09T18:22:41', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2b98d84c-74f7-4b55-886e-380d6bbd107e'	System	09 Sep 2020 23:24:06
User entered '09 Sep 2020 18:22'	System	09 Sep 2020 23:24:06

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 7'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:10', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:12', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:17', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'None (0)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered 'No (N)'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-09-10T22:11:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '34571d99-727f-4f85-9083-d8de5c9c4c14'	System	11 Sep 2020 03:12:49
User entered '10 Sep 2020 22:11'	System	11 Sep 2020 03:12:49

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:44:02

US3912113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:23:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 22:49:42

US3912113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:23:00
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 22:49:42

US3912113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:23:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 22:49:42

US3912113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:23:00
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:49:42

US3912113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:23:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 22:50:54

US3912113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	11 Sep 2020 22:50:54

US3912113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:11
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 22:10:37

US3912113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:11
User entered '18 Sep 2020'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 22:10:37

US3912113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:11
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 22:10:37

US3912113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:11
User entered empty.	Amy Collins (b) (4) (b) (4)	18 Sep 2020 22:10:37

US3912113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:00
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	18 Sep 2020 22:10:43

US3912113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	18 Sep 2020 22:10:43

US3912113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:30
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	25 Sep 2020 20:15:36

US3912113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:30
User entered '25 Sep 2020'	Monique Gawlik (b) (4)	25 Sep 2020 20:15:36

US3912113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:30
User entered 'Contact Made (CONTACT MADE)'	Monique Gawlik (b) (4)	25 Sep 2020 20:15:36

US3912113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:30
User entered empty.	Monique Gawlik (b) (4)	25 Sep 2020 20:15:36

US3912113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:52:54
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	25 Sep 2020 20:15:24

US3912113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	25 Sep 2020 20:15:24

US3912113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:46:34
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:11

US3912113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:46:34
User entered '02 Oct 2020'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:11

US3912113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:46:34
User entered 'Clinic (Clinic)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:11

US3912113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'VISIT2'	System	02 Oct 2020 18:55:11

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User entered '02 Oct 2020'	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User entered '13:17'	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '02 Oct 2020 13:17'	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Oct 2020 19:09:38
User entered '37.3' C reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Oct 2020 19:08:05
User entered '37' (non-conformant).	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:09:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Oct 2020 19:09:38
User entered '77' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:08:05
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'bpm'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:09:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Oct 2020 19:09:38
User entered '12' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:08:05
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'breaths/min'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:09:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Oct 2020 19:09:38
User entered '96' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:08:05
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 06:59:58
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Data is correct, NCS' (Site from System).	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:10:06
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Oct 2020 19:09:38
User closed query 'Data is required. Please provide.' System (Site from System).		12 Oct 2020 19:09:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		12 Oct 2020 19:09:38
User entered '56' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Oct 2020 19:08:05
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:09:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 19:09:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:09:38
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:08:05
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '02 Oct 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '15:15' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '02 Oct 2020 15:15'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '37.1' C reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered empty.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '77' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'bpm'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '14' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'breaths/min'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '107' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:54
User entered '69' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:09:38
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	12 Oct 2020 19:09:38
User entered empty.	System	12 Oct 2020 19:08:05

US3912113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:45
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:27

US3912113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:45
User entered '02 Oct 2020'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:27

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered '02 Oct 2020'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered 'Urine (URINE)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered 'Negative (NEGATIVE)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered 'No (N)'	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered empty.	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:48:37
User entered empty.	Amy Collins (b) (4) (b) (4)	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered empty.	System	02 Oct 2020 18:55:43

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered '2 Oct 2020'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered '14:44'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '2 Oct 2020 14:44'	System	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 16:49:29
User entered 'ONCE'	System	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:48:45

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 20:06:45

US3912113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:03
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:24

US3912113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:03
User entered '2 Oct 2020'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:24

US3912113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:03
User entered '13:56'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:24

US3912113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '2 Oct 2020 13:56'	System	02 Oct 2020 20:07:24

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:14
User entered '2 Oct 2020'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:14
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:14
User entered '14:01'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '2 Oct 2020 14:01'	System	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:14
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:49:14
User entered empty.	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered empty.	System	02 Oct 2020 20:07:55

US3912113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:50:13
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	02 Oct 2020 20:08:03

US3912113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '1'	System	02 Oct 2020 20:08:03

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2eea8336-2785-4c74-9bf7-8776f0653bfd'	System	02 Oct 2020 20:17:49
User entered 'Yes (Y)'	System	02 Oct 2020 20:17:49

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:10', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2eea8336-2785-4c74-9bf7-8776f0653bfd'	System	02 Oct 2020 20:17:49
User entered '98.8'	System	02 Oct 2020 20:17:49

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:16', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2eea8336-2785-4c74-9bf7-8776f0653bfd'	System	02 Oct 2020 20:17:49
User entered 'No (N)'	System	02 Oct 2020 20:17:49

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '2eea8336-2785-4c74-9bf7-8776f0653bfd'	System	02 Oct 2020 20:17:49
User entered '02 Oct 2020 15:16'	System	02 Oct 2020 20:17:49

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 15:04'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 17:34'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:11:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '635a6f22-c587-489d-bc47-05345085b812'	System	03 Oct 2020 01:13:44
User entered 'Yes (Y)'	System	03 Oct 2020 01:13:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:12:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '635a6f22-c587-489d-bc47-05345085b812'	System	03 Oct 2020 01:13:44
User entered '98.6'	System	03 Oct 2020 01:13:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:12:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '635a6f22-c587-489d-bc47-05345085b812'	System	03 Oct 2020 01:13:44
User entered 'No (N)'	System	03 Oct 2020 01:13:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:12:16', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '635a6f22-c587-489d-bc47-05345085b812'	System	03 Oct 2020 01:13:44
User entered '02 Oct 2020 20:12'	System	03 Oct 2020 01:13:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 18:29'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 2'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:58:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	System	03 Oct 2020 18:00:44
User entered 'Yes (Y)'	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:04', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	System	03 Oct 2020 18:00:44
User entered '99.2'	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	System	03 Oct 2020 18:00:44
User entered 'Yes (Y)'	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted and confirms use of Tylenol extra strength for pain at the injection site' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 15:04:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Sandra Clancy (b) (4)	09 Oct 2020 21:24:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:14', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	(b) (4)	
User entered '1'	System	03 Oct 2020 18:00:44
	System	03 Oct 2020 18:00:44
	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:14', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	System	03 Oct 2020 18:00:44
User entered '0'	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:16', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b03ea120-b273-410c-8f2e-e643075b76dd'	System	03 Oct 2020 18:00:44
User entered '03 Oct 2020 12:59'	System	03 Oct 2020 18:00:44

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 3'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:35:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	System	05 Oct 2020 00:37:35
User entered 'Yes (Y)'	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:35:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	System	05 Oct 2020 00:37:35
User entered '100.1'	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:35:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	System	05 Oct 2020 00:37:35
User entered 'Yes (Y)'	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject confirms that Tylenol extra strength was used for pain at the injection site.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 15:04:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:35:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:27:02
User entered '1'	System	05 Oct 2020 00:37:35
	System	05 Oct 2020 00:37:35
	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:35:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	System	05 Oct 2020 00:37:35
User entered '0'	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:02', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a4ff44de-041f-43c1-b4dc-ccf3cca8f0cf'	System	05 Oct 2020 00:37:35
User entered '04 Oct 2020 19:36'	System	05 Oct 2020 00:37:35

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 4'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:04', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '62142a07-9d24-4a52-ada8-e0305e2ceef'	System	05 Oct 2020 22:23:45
User entered 'Yes (Y)'	System	05 Oct 2020 22:23:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '62142a07-9d24-4a52-ada8-e0305e2ceef'	System	05 Oct 2020 22:23:45
User entered '99.5'	System	05 Oct 2020 22:23:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '62142a07-9d24-4a52-ada8-e0305e2ceef'	System	05 Oct 2020 22:23:45
User entered 'No (N)'	System	05 Oct 2020 22:23:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:14', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '62142a07-9d24-4a52-ada8-e0305e2ceef'	System	05 Oct 2020 22:23:45
User entered '05 Oct 2020 17:22'	System	05 Oct 2020 22:23:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 5'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:06', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '88015f68-91f9-4b8a-8659-3132475c9448'	System	06 Oct 2020 20:08:47
User entered 'Yes (Y)'	System	06 Oct 2020 20:08:47

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '88015f68-91f9-4b8a-8659-3132475c9448'	System	06 Oct 2020 20:08:47
User entered '97.9'	System	06 Oct 2020 20:08:47

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '88015f68-91f9-4b8a-8659-3132475c9448'	System	06 Oct 2020 20:08:47
User entered 'No (N)'	System	06 Oct 2020 20:08:47

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '88015f68-91f9-4b8a-8659-3132475c9448'	System	06 Oct 2020 20:08:47
User entered '06 Oct 2020 15:07'	System	06 Oct 2020 20:08:47

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 6'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5d60ede8-d29e-44d8-af6f-047ac07a7fd2'	System	08 Oct 2020 01:18:07
User entered 'Yes (Y)'	System	08 Oct 2020 01:18:07

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5d60ede8-d29e-44d8-af6f-047ac07a7fd2'	System	08 Oct 2020 01:18:07
User entered '98.6'	System	08 Oct 2020 01:18:07

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:33', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5d60ede8-d29e-44d8-af6f-047ac07a7fd2'	System	08 Oct 2020 01:18:07
User entered 'No (N)'	System	08 Oct 2020 01:18:07

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5d60ede8-d29e-44d8-af6f-047ac07a7fd2'	System	08 Oct 2020 01:18:07
User entered '07 Oct 2020 20:16'	System	08 Oct 2020 01:18:07

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 7'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:24:49', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '884e47c5-4985-438b-a49d-2175fc7a225b'	System	09 Oct 2020 05:25:01
User entered 'Yes (Y)'	System	09 Oct 2020 05:25:01

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:24:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '884e47c5-4985-438b-a49d-2175fc7a225b'	System	09 Oct 2020 05:25:01
User entered '98.4'	System	09 Oct 2020 05:25:01

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:24:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '884e47c5-4985-438b-a49d-2175fc7a225b'	System	09 Oct 2020 05:25:01
User entered 'No (N)'	System	09 Oct 2020 05:25:01

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:24:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '884e47c5-4985-438b-a49d-2175fc7a225b'	System	09 Oct 2020 05:25:01
User entered '09 Oct 2020 00:24'	System	09 Oct 2020 05:25:01

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:34', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '561f37bc-5120-4cb6-9824-1bcf6c4cb4be'	System	02 Oct 2020 20:18:19
User entered 'None (1)'	System	02 Oct 2020 20:18:19

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:36', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '561f37bc-5120-4cb6-9824-1bcf6c4cb4be'	System	02 Oct 2020 20:18:19
User entered 'No (N)'	System	02 Oct 2020 20:18:19

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '561f37bc-5120-4cb6-9824-1bcf6c4cb4be'	System	02 Oct 2020 20:18:19
User entered 'No (N)'	System	02 Oct 2020 20:18:19

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:47', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '561f37bc-5120-4cb6-9824-1bcf6c4cb4be'	System	02 Oct 2020 20:18:19
User entered 'None (1)'	System	02 Oct 2020 20:18:19

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:16:51', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '561f37bc-5120-4cb6-9824-1bcf6c4cb4be'	System	02 Oct 2020 20:18:19
User entered '02 Oct 2020 15:16'	System	02 Oct 2020 20:18:19

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 15:04'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 17:34'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:12:34', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '52fdbbeb-a98d-445b-8110-4092704607ff'	System	03 Oct 2020 01:15:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 01:15:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:12:36', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '52fdbbeb-a98d-445b-8110-4092704607ff'	System	03 Oct 2020 01:15:16
User entered 'No (N)'	System	03 Oct 2020 01:15:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:13:36', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '52fdbbeb-a98d-445b-8110-4092704607ff'	System	03 Oct 2020 01:15:16
User entered 'No (N)'	System	03 Oct 2020 01:15:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:13:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '52fdbbeb-a98d-445b-8110-4092704607ff'	System	03 Oct 2020 01:15:16
User entered 'None (1)'	System	03 Oct 2020 01:15:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:13:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '52fdbbeb-a98d-445b-8110-4092704607ff'	System	03 Oct 2020 01:15:16
User entered '02 Oct 2020 20:13'	System	03 Oct 2020 01:15:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 18:29'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 2'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '24955bf3-4f9e-4f66-b65a-a3629c66efd0'	System	03 Oct 2020 18:00:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 18:00:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '24955bf3-4f9e-4f66-b65a-a3629c66efd0'	System	03 Oct 2020 18:00:59
User entered 'No (N)'	System	03 Oct 2020 18:00:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:25', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '24955bf3-4f9e-4f66-b65a-a3629c66efd0'	System	03 Oct 2020 18:00:59
User entered 'No (N)'	System	03 Oct 2020 18:00:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:27', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '24955bf3-4f9e-4f66-b65a-a3629c66efd0'	System	03 Oct 2020 18:00:59
User entered 'None (1)'	System	03 Oct 2020 18:00:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '24955bf3-4f9e-4f66-b65a-a3629c66efd0'	System	03 Oct 2020 18:00:59
User entered '03 Oct 2020 12:59'	System	03 Oct 2020 18:00:59

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 3'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered 'Yes (Y)'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered '40'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:33', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered 'No (N)'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered 'None (1)'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '21f578aa-48cc-4cab-9055-9b3a9bf35280'	System	05 Oct 2020 00:38:08
User entered '04 Oct 2020 19:36'	System	05 Oct 2020 00:38:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 4'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '40252efb-a91b-450d-854b-710f3ebf9267'	System	05 Oct 2020 22:24:08
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 22:24:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:25', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '40252efb-a91b-450d-854b-710f3ebf9267'	System	05 Oct 2020 22:24:08
User entered 'No (N)'	System	05 Oct 2020 22:24:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:27', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '40252efb-a91b-450d-854b-710f3ebf9267'	System	05 Oct 2020 22:24:08
User entered 'No (N)'	System	05 Oct 2020 22:24:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '40252efb-a91b-450d-854b-710f3ebf9267'	System	05 Oct 2020 22:24:08
User entered 'None (1)'	System	05 Oct 2020 22:24:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:34', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '40252efb-a91b-450d-854b-710f3ebf9267'	System	05 Oct 2020 22:24:08
User entered '05 Oct 2020 17:22'	System	05 Oct 2020 22:24:08

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 5'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b24de89e-8ac1-4ad8-bbed-83ebb46a4447'	System	06 Oct 2020 20:09:09
User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 20:09:09

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:23', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b24de89e-8ac1-4ad8-bbed-83ebb46a4447'	System	06 Oct 2020 20:09:09
User entered 'No (N)'	System	06 Oct 2020 20:09:09

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:25', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b24de89e-8ac1-4ad8-bbed-83ebb46a4447'	System	06 Oct 2020 20:09:09
User entered 'No (N)'	System	06 Oct 2020 20:09:09

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:28', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b24de89e-8ac1-4ad8-bbed-83ebb46a4447'	System	06 Oct 2020 20:09:09
User entered 'None (1)'	System	06 Oct 2020 20:09:09

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'b24de89e-8ac1-4ad8-bbed-83ebb46a4447'	System	06 Oct 2020 20:09:09
User entered '06 Oct 2020 15:07'	System	06 Oct 2020 20:09:09

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 6'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '76d39fda-0009-4657-b1d2-bfbd6989e91f'	System	08 Oct 2020 01:18:25
User entered 'None (1)'	System	08 Oct 2020 01:18:25

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '76d39fda-0009-4657-b1d2-bfbd6989e91f'	System	08 Oct 2020 01:18:25
User entered 'No (N)'	System	08 Oct 2020 01:18:25

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:50', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '76d39fda-0009-4657-b1d2-bfbd6989e91f'	System	08 Oct 2020 01:18:25
User entered 'No (N)'	System	08 Oct 2020 01:18:25

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '76d39fda-0009-4657-b1d2-bfbd6989e91f'	System	08 Oct 2020 01:18:25
User entered 'None (1)'	System	08 Oct 2020 01:18:25

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '76d39fda-0009-4657-b1d2-bfbd6989e91f'	System	08 Oct 2020 01:18:25
User entered '07 Oct 2020 20:16'	System	08 Oct 2020 01:18:25

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 7'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0a2b06d0-75a4-4790-b329-acc7325d813d'	System	09 Oct 2020 05:25:16
User entered 'None (1)'	System	09 Oct 2020 05:25:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0a2b06d0-75a4-4790-b329-acc7325d813d'	System	09 Oct 2020 05:25:16
User entered 'No (N)'	System	09 Oct 2020 05:25:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0a2b06d0-75a4-4790-b329-acc7325d813d'	System	09 Oct 2020 05:25:16
User entered 'No (N)'	System	09 Oct 2020 05:25:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:09', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0a2b06d0-75a4-4790-b329-acc7325d813d'	System	09 Oct 2020 05:25:16
User entered 'None (1)'	System	09 Oct 2020 05:25:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0a2b06d0-75a4-4790-b329-acc7325d813d'	System	09 Oct 2020 05:25:16
User entered '09 Oct 2020 00:25'	System	09 Oct 2020 05:25:16

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:11', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:14', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:16', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:18', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'None (0)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered 'No (N)'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T15:17:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '395fa606-5f06-4ca3-9cad-1d61cb41c940'	System	02 Oct 2020 20:18:52
User entered '02 Oct 2020 15:17'	System	02 Oct 2020 20:18:52

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 15:04'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 17:34'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:13:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'None (0)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'Some interference with activity (2)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'None (0)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:05', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'None (0)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:06', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'None (0)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:15', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'None (0)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered 'No (N)'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-02T20:14:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '80d10a1b-4689-445a-8594-c4d40c2efa67'	System	03 Oct 2020 01:15:48
User entered '02 Oct 2020 20:14'	System	03 Oct 2020 01:15:48

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '02 Oct 2020 18:29'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 2'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:40', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'Significant; prevents daily activity (3)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'Some interference with activity (2)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'No interference with activity (1)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:50', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'None (0)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:56', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered 'No (N)'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-03T12:59:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'c3eb4f1a-d63f-49c7-9e18-3b8cf77f4177'	System	03 Oct 2020 18:01:26
User entered '03 Oct 2020 12:59'	System	03 Oct 2020 18:01:26

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 3'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'No interference with activity (1)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'Some interference with activity (2)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:51', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'No interference with activity (1)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'No interference with activity (1)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:36:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'None (0)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:37:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered 'No (N)'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-04T19:37:02', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'ec5e11c4-a18c-4560-9444-eb372cb68f'	System	05 Oct 2020 00:38:36
User entered '04 Oct 2020 19:37'	System	05 Oct 2020 00:38:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 4'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'No interference with activity (1)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'Some interference with activity (2)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:44', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'None (0)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'None (0)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:47', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'None (0)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:50', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'No interference with activity (1)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:52', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered 'No (N)'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-05T17:22:54', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '99725505-a6d4-4edd-8ff3-d6d76e4c08f5'	System	05 Oct 2020 22:24:27
User entered '05 Oct 2020 17:22'	System	05 Oct 2020 22:24:27

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 5'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:43', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'None (0)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:45', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'Some interference with activity (2)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:47', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'None (0)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:49', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'None (0)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:07:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'None (0)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:08:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered 'No (N)'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-06T15:08:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '54b311b8-bd16-438b-ace2-e3f8461b659a'	System	06 Oct 2020 20:09:35
User entered '06 Oct 2020 15:08'	System	06 Oct 2020 20:09:35

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 6'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:16:59', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'None (0)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'No interference with activity (1)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'None (0)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:04', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'None (0)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:06', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'None (0)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:08', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'None (0)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:10', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered 'No (N)'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-07T20:17:12', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4ec202c9-919b-473b-afe7-46a397eafb6b'	System	08 Oct 2020 01:18:45
User entered '07 Oct 2020 20:17'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	02 Oct 2020 20:06:45
User entered 'Day 7'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:19', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'None (0)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:23', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'None (0)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'None (0)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'None (0)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:27', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'None (0)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered 'No (N)'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-09T00:25:32', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '3ea6e468-ec1e-4cc1-833e-d091dd377c58'	System	09 Oct 2020 05:25:36
User entered '09 Oct 2020 00:25'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:06:45

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	09 Oct 2020 05:25:36
User entered 'Day 8'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Oct 2020 12:00'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	09 Oct 2020 05:25:36
User entered 'Day 9'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-10T16:23:17', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7523c710-eb56-4b3d-ae7c-faca70b0d35e'	System	10 Oct 2020 21:23:22
User entered 'None (0)'	System	10 Oct 2020 21:23:22

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-10T16:23:20', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '7523c710-eb56-4b3d-ae7c-faca70b0d35e'	System	10 Oct 2020 21:23:22
User entered '10 Oct 2020 16:23'	System	10 Oct 2020 21:23:22

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	08 Oct 2020 01:18:45
User entered 'Day 8'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 01:18:45

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	09 Oct 2020 05:25:36
User entered 'Day 9'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

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)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-10T16:23:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '337b5d3a-3456-4978-b8ab-b7fed04747d6'	System	10 Oct 2020 21:23:28
User entered 'No (N)'	System	10 Oct 2020 21:23:28

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-10-10T16:23:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '337b5d3a-3456-4978-b8ab-b7fed04747d6'	System	10 Oct 2020 21:23:28
User entered '10 Oct 2020 16:23'	System	10 Oct 2020 21:23:28

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 05:25:36

US3912113

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:48:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 05:25:36

US3912113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:51:07
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:23:44

US3912113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:51:07
User entered '9 Oct 2020'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:23:44

US3912113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:51:07
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:23:44

US3912113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:51:07
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:23:44

US3912113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:54:06
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:23:49

US3912113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	09 Oct 2020 21:23:49

US3912113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:12
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:29:40

US3912113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:12
User entered '16 Oct 2020'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:29:40

US3912113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:12
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:29:40

US3912113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:12
User entered empty.	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:29:40

US3912113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:33
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	16 Oct 2020 18:29:43

US3912113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	16 Oct 2020 18:29:43

US3912113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 30OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 10:42:46
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 30OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'Lab collected REQ # 1F607154757' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:06:45
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 30OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:51:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:51:39
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:25:53

US3912113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:39
User entered '23 Oct 2020'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:25:53

US3912113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:39
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:25:53

US3912113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:39
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:25:53

US3912113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:51:43
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 21:25:58

US3912113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	23 Oct 2020 21:25:58

US3912113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:28
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:40:15

US3912113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:28
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:40:15

US3912113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:28
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:40:15

US3912113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'VISIT3'	System	16 Nov 2020 15:40:15

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '13:37'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '30 Oct 2020 13:37'	System	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '36.6' C	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered empty.	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '68'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'bpm'	System	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '12'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'breaths/min'	System	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '103'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '62'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'mmHg'	System	16 Nov 2020 15:41:05

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22

US3912113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22

US3912113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:07
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:17

US3912113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:07
User entered empty.	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:17

US3912113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:01
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:39

US3912113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:01
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:39

US3912113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:01
User entered '13:52'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:39

US3912113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '30 Oct 2020 13:52'	System	16 Nov 2020 15:41:39

US3912113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:14
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 15:41:44

US3912113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered '1'	System	16 Nov 2020 15:41:44

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 64'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 71'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-11-11T15:38:25', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '58b7c0b2-2202-46f1-9437-7b16fc76cfd8'	System	11 Nov 2020 21:38:40
User entered 'No (N)'	System	11 Nov 2020 21:38:40

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-11-11T15:38:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '58b7c0b2-2202-46f1-9437-7b16fc76cfd8'	System	11 Nov 2020 21:38:40
User entered 'No (N)'	System	11 Nov 2020 21:38:40

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-11-11T15:38:36', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '58b7c0b2-2202-46f1-9437-7b16fc76cfd8'	System	11 Nov 2020 21:38:40
User entered '11 Nov 2020 15:38:36'	System	11 Nov 2020 21:38:40

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered 'Day 78'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 20:44:02

US3912113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:11:14
Data entry locked.	System	04 Sep 2020 20:44:02
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 20:44:02

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-11-22T00:13:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a3c594db-0698-474e-87fb-45601e3ba2f5'	System	22 Nov 2020 06:13:12
User entered 'No (N)'	System	22 Nov 2020 06:13:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-11-22T00:13:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a3c594db-0698-474e-87fb-45601e3ba2f5'	System	22 Nov 2020 06:13:12
User entered 'No (N)'	System	22 Nov 2020 06:13:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-11-22T00:13:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'a3c594db-0698-474e-87fb-45601e3ba2f5'	System	22 Nov 2020 06:13:12
User entered '22 Nov 2020 00:13:07'	System	22 Nov 2020 06:13:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-11-29T00:12:30', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '121a67e7-7c59-49e3-b9a6-333fe2d5503e'	System	29 Nov 2020 06:12:38
User entered 'No (N)'	System	29 Nov 2020 06:12:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2020-11-29T00:12:33', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '121a67e7-7c59-49e3-b9a6-333fe2d5503e'	System	29 Nov 2020 06:12:38
User entered 'No (N)'	System	29 Nov 2020 06:12:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-11-29T00:12:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '121a67e7-7c59-49e3-b9a6-333fe2d5503e'	System	29 Nov 2020 06:12:38
User entered '29 Nov 2020 00:12:35'	System	29 Nov 2020 06:12:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-12-08T18:49:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '35ab0ac5-288b-4afa-9471-0f799178c8df'	System	09 Dec 2020 00:50:04
User entered 'No (N)'	System	09 Dec 2020 00:50:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2020-12-08T18:49:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '35ab0ac5-288b-4afa-9471-0f799178c8df'	System	09 Dec 2020 00:50:04
User entered 'No (N)'	System	09 Dec 2020 00:50:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-12-08T18:50:01', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '35ab0ac5-288b-4afa-9471-0f799178c8df'	System	09 Dec 2020 00:50:04
User entered '08 Dec 2020 18:50:01'	System	09 Dec 2020 00:50:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-12-13T09:55:48', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bef40a99-e4a2-4106-ac33-0e4ce157c142'	System	13 Dec 2020 16:55:55
User entered 'No (N)'	System	13 Dec 2020 16:55:55

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-12-13T09:55:50', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bef40a99-e4a2-4106-ac33-0e4ce157c142'	System	13 Dec 2020 16:55:55
User entered 'No (N)'	System	13 Dec 2020 16:55:55

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-12-13T09:55:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'bef40a99-e4a2-4106-ac33-0e4ce157c142'	System	13 Dec 2020 16:55:55
User entered '13 Dec 2020 09:55:53'	System	13 Dec 2020 16:55:55

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-12-20T00:02:21', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '48fb314e-9d81-4cb0-8d7b-9d59a9e812f2'	System	20 Dec 2020 07:02:24
User entered 'No (N)'	System	20 Dec 2020 07:02:24

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2020-12-20T00:02:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '48fb314e-9d81-4cb0-8d7b-9d59a9e812f2'	System	20 Dec 2020 07:02:24
User entered 'No (N)'	System	20 Dec 2020 07:02:24

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-12-20T00:02:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '48fb314e-9d81-4cb0-8d7b-9d59a9e812f2'	System	20 Dec 2020 07:02:24
User entered '20 Dec 2020 00:02:26'	System	20 Dec 2020 07:02:24

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2020-12-27T00:02:14', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4b3638cd-76a9-4abd-9e2c-4c07cc357d1d'	System	27 Dec 2020 06:02:42
User entered 'No (N)'	System	27 Dec 2020 06:02:42

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2020-12-27T00:02:17', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4b3638cd-76a9-4abd-9e2c-4c07cc357d1d'	System	27 Dec 2020 06:02:42
User entered 'No (N)'	System	27 Dec 2020 06:02:42

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2020-12-27T00:02:20', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '4b3638cd-76a9-4abd-9e2c-4c07cc357d1d'	System	27 Dec 2020 06:02:42
User entered '27 Dec 2020 00:02:20'	System	27 Dec 2020 06:02:42

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-03T00:36:49', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '30575f4c-6210-4bc0-b52f-186cc977830a'	System	03 Jan 2021 06:37:15
User entered 'No (N)'	System	03 Jan 2021 06:37:15

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-03T00:36:53', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '30575f4c-6210-4bc0-b52f-186cc977830a'	System	03 Jan 2021 06:37:15
User entered 'No (N)'	System	03 Jan 2021 06:37:15

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-03T00:36:55', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '30575f4c-6210-4bc0-b52f-186cc977830a'	System	03 Jan 2021 06:37:15
User entered '03 Jan 2021 00:36:55'	System	03 Jan 2021 06:37:15

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-10T00:29:33', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'Yes (Y)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-01-10T00:29:38', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'Yes (Y)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

Please 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 (999883a6c8d1f80f)', Time: '2021-01-10T00:29:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:29:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'Yes (Y)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '1'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '1'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '1'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '1'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '0'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:03', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '1'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

Please 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 (999883a6c8d1f80f)', Time: '2021-01-10T00:30:07', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:10', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered 'No (N)'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-10T00:30:13', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8ab876ca-a2da-4988-b96d-dabccbe8776c'	System	10 Jan 2021 06:30:33
User entered '10 Jan 2021 00:30:13'	System	10 Jan 2021 06:30:33

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-17T12:59:35', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '227adbff-b494-4cd6-bb9b-1dcd9170d648'	System	17 Jan 2021 18:59:50
User entered 'No (N)'	System	17 Jan 2021 18:59:50

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-01-17T12:59:37', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '227adbff-b494-4cd6-bb9b-1dcd9170d648'	System	17 Jan 2021 18:59:50
User entered 'No (N)'	System	17 Jan 2021 18:59:50

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-17T12:59:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '227adbff-b494-4cd6-bb9b-1dcd9170d648'	System	17 Jan 2021 18:59:50
User entered '17 Jan 2021 12:59:39'	System	17 Jan 2021 18:59:50

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-24T18:34:22', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '70b21ca6-ca80-4429-b1e4-165dc176007e'	System	25 Jan 2021 00:34:30
User entered 'No (N)'	System	25 Jan 2021 00:34:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-01-24T18:34:24', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '70b21ca6-ca80-4429-b1e4-165dc176007e'	System	25 Jan 2021 00:34:30
User entered 'No (N)'	System	25 Jan 2021 00:34:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-24T18:34:26', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '70b21ca6-ca80-4429-b1e4-165dc176007e'	System	25 Jan 2021 00:34:30
User entered '24 Jan 2021 18:34:26'	System	25 Jan 2021 00:34:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-01-31T00:27:49', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '89eec729-551f-4aef-be97-136932a27164'	System	31 Jan 2021 06:28:05
User entered 'No (N)'	System	31 Jan 2021 06:28:05

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-01-31T00:27:58', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '89eec729-551f-4aef-be97-136932a27164'	System	31 Jan 2021 06:28:05
User entered 'No (N)'	System	31 Jan 2021 06:28:05

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-01-31T00:28:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '89eec729-551f-4aef-be97-136932a27164' User entered '31 Jan 2021 00:28:00'	System	31 Jan 2021 06:28:05
	System	31 Jan 2021 06:28:05

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-02-07T00:40:39', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8e6a9097-6110-44fd-adcf-5eae6cfc8134'	System	07 Feb 2021 06:41:12
User entered 'No (N)'	System	07 Feb 2021 06:41:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-02-07T00:40:42', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8e6a9097-6110-44fd-adcf-5eae6cfc8134'	System	07 Feb 2021 06:41:12
User entered 'No (N)'	System	07 Feb 2021 06:41:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-02-07T00:40:46', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '8e6a9097-6110-44fd-adcf-5eae6cfc8134'	System	07 Feb 2021 06:41:12
User entered '07 Feb 2021 00:40:46'	System	07 Feb 2021 06:41:12

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-02-14T00:13:04', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e44a081f-c0aa-49c1-9b5f-91063c7ef964'	System	14 Feb 2021 06:13:30
User entered 'No (N)'	System	14 Feb 2021 06:13:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-02-14T00:13:06', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e44a081f-c0aa-49c1-9b5f-91063c7ef964'	System	14 Feb 2021 06:13:30
User entered 'No (N)'	System	14 Feb 2021 06:13:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-02-14T00:13:08', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e44a081f-c0aa-49c1-9b5f-91063c7ef964'	System	14 Feb 2021 06:13:30
User entered '14 Feb 2021 00:13:08'	System	14 Feb 2021 06:13:30

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-02-22T10:38:27', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '224c8dab-877b-41a1-bf02-26f2a4886539'	System	22 Feb 2021 16:38:57
User entered 'No (N)'	System	22 Feb 2021 16:38:57

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-02-22T10:38:29', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '224c8dab-877b-41a1-bf02-26f2a4886539'	System	22 Feb 2021 16:38:57
User entered 'No (N)'	System	22 Feb 2021 16:38:57

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-02-22T10:38:31', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '224c8dab-877b-41a1-bf02-26f2a4886539'	System	22 Feb 2021 16:38:57
User entered '22 Feb 2021 10:38:31'	System	22 Feb 2021 16:38:57

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-03-01T23:19:09-07:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'cb7f3c07-e5f9-45bc-85a6-eba054c58d53'	System	02 Mar 2021 05:19:38
User entered 'No (N)'	System	02 Mar 2021 05:19:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-03-01T23:19:11-07:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'cb7f3c07-e5f9-45bc-85a6-eba054c58d53'	System	02 Mar 2021 05:19:38
User entered 'No (N)'	System	02 Mar 2021 05:19:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-03-01T23:19:18-07:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'cb7f3c07-e5f9-45bc-85a6-eba054c58d53'	System	02 Mar 2021 05:19:38
User entered '01 Mar 2021 23:19:18'	System	02 Mar 2021 05:19:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-03-25T11:02:27-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c3ae8ca-d5cc-4167-b0a3-dcd6b89faaf6'	System	25 Mar 2021 16:11:29
User entered 'No (N)'	System	25 Mar 2021 16:11:29

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-03-25T11:02:29-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c3ae8ca-d5cc-4167-b0a3-dcd6b89faaf6'	System	25 Mar 2021 16:11:29
User entered 'No (N)'	System	25 Mar 2021 16:11:29

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-03-25T11:02:31-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '0c3ae8ca-d5cc-4167-b0a3-dcd6b89faaf6'	System	25 Mar 2021 16:11:29
User entered '25 Mar 2021 11:02:31'	System	25 Mar 2021 16:11:29

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-03-28T10:08:51-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd469b5e2-9a70-4462-a33b-bc790c1355ef' User entered 'No (N)'	System	28 Mar 2021 15:09:28
	System	28 Mar 2021 15:09:28

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-03-28T10:08:52-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd469b5e2-9a70-4462-a33b-bc790c1355ef'	System	28 Mar 2021 15:09:28
User entered 'No (N)'	System	28 Mar 2021 15:09:28

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-03-28T10:08:57-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'd469b5e2-9a70-4462-a33b-bc790c1355ef' User entered '28 Mar 2021 10:08:57'	System	28 Mar 2021 15:09:28
	System	28 Mar 2021 15:09:28

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-04-05T15:23:06-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '422ce1cb-ac03-4a6d-a234-d8d58bd4ed87' User entered 'No (N)'	System	05 Apr 2021 20:23:34
	System	05 Apr 2021 20:23:34

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-04-05T15:23:08-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '422ce1cb-ac03-4a6d-a234-d8d58bd4ed87'	System	05 Apr 2021 20:23:34
User entered 'No (N)'	System	05 Apr 2021 20:23:34

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-04-05T15:23:11-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '422ce1cb-ac03-4a6d-a234-d8d58bd4ed87'	System	05 Apr 2021 20:23:34
User entered '05 Apr 2021 15:23:11'	System	05 Apr 2021 20:23:34

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-04-12T15:24:19-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5b1f29d9-8abb-441c-82b2-8aa6a29e58b1' User entered 'No (N)'	System	12 Apr 2021 20:24:48
	System	12 Apr 2021 20:24:48

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-04-12T15:24:21-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5b1f29d9-8abb-441c-82b2-8aa6a29e58b1'	System	12 Apr 2021 20:24:48
User entered 'No (N)'	System	12 Apr 2021 20:24:48

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-04-12T15:24:24-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '5b1f29d9-8abb-441c-82b2-8aa6a29e58b1' User entered '12 Apr 2021 15:24:24'	System	12 Apr 2021 20:24:48
	System	12 Apr 2021 20:24:48

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-04-18T00:05:41-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '670a0ece-5fd4-4e01-9c44-dd1b264381ef' User entered 'No (N)'	System	18 Apr 2021 05:06:04
	System	18 Apr 2021 05:06:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-04-18T00:05:43-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '670a0ece-5fd4-4e01-9c44-dd1b264381ef'	System	18 Apr 2021 05:06:04
User entered 'No (N)'	System	18 Apr 2021 05:06:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-04-18T00:05:45-06:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '670a0ece-5fd4-4e01-9c44-dd1b264381ef' User entered '18 Apr 2021 00:05:45'	System	18 Apr 2021 05:06:04
	System	18 Apr 2021 05:06:04

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-04-25T10:53:42-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '71afc446-73e3-48ca-af6e-6290da25e811'	System	25 Apr 2021 15:53:49
User entered 'No (N)'	System	25 Apr 2021 15:53:49

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-04-25T10:53:43-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '71afc446-73e3-48ca-af6e-6290da25e811'	System	25 Apr 2021 15:53:49
User entered 'No (N)'	System	25 Apr 2021 15:53:49

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-04-25T10:53:45-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '71afc446-73e3-48ca-af6e-6290da25e811'	System	25 Apr 2021 15:53:49
User entered '25 Apr 2021 10:53:45'	System	25 Apr 2021 15:53:49

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[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 (999883a6c8d1f80f)', Time: '2021-05-02T22:51:15-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered 'Yes (Y)'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

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 (999883a6c8d1f80f)', Time: '2021-05-02T22:51:18-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered 'No (N)'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-05-02T22:51:20-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered 'No (N)'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-05-02T22:51:27-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered 'Yes (Y)'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Please 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 (999883a6c8d1f80f)', Time: '2021-05-02T22:51:30-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-05-02T22:51:33-05:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: 'e60bc567-fd78-44db-a0d1-4d703a555a4e'	System	03 May 2021 03:52:38
User entered '02 May 2021 22:51:33'	System	03 May 2021 03:52:38

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:11:14

US3912113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:48:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:11:14
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:11:14

US3912113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:48:45

[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)	24 Apr 2021 07:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-03-01T23:19:50-07:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '818fdafc-a1c5-404b-8237-48de5e7c434b'	System	02 Mar 2021 05:20:11
User entered 'No (N)'	System	02 Mar 2021 05:20:11

US3912113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:48:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:04:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (999883a6c8d1f80f)', Time: '2021-03-01T23:19:52-07:00', User OID: 'PatientReportedOutcome (US3912113)', ODM File OID: '818fdafc-a1c5-404b-8237-48de5e7c434b' User entered '01 Mar 2021 23:19:52'	System	02 Mar 2021 05:20:11
	System	02 Mar 2021 05:20:11

US3912113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 01:42:52

US3912113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:18
User entered '30 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 01:42:52

US3912113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 01:42:52

US3912113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:24:18
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:52

US3912113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:25:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 01:42:59

US3912113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:22
User entered 'I'	System	01 Dec 2020 01:42:59

US3912113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:55:16
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	30 Dec 2020 21:16:55

US3912113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:55:16
User entered '30 Dec 2020'	Monique Gawlik (b) (4)	30 Dec 2020 21:16:55

US3912113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:55:16
User entered 'Contact Made (CONTACT MADE)'	Monique Gawlik (b) (4)	30 Dec 2020 21:16:55

US3912113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:55:16
User entered empty.	Monique Gawlik (b) (4)	30 Dec 2020 21:16:55

US3912113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:55:21
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	30 Dec 2020 21:17:05

US3912113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User entered 'I'	System	30 Dec 2020 21:17:05

US3912113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:35:53
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 14:55:33

US3912113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:35:53
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 14:55:33

US3912113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:35:53
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 14:55:33

US3912113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:35:53
User entered empty.	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 14:55:33

US3912113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:36:25
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 14:55:54

US3912113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User entered 'I'	System	03 Feb 2021 14:55:54

US3912113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:33:50
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 00:00:06

US3912113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:33:50
User entered '1 Mar 2021'	Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 00:00:06

US3912113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:33:50
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 00:00:06

US3912113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:48:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:33:50
User entered empty.	Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 00:00:06

US3912113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:34:27
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 00:00:38

US3912113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:00:07
User entered 'I'	System	02 Mar 2021 00:00:38

US3912113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:21:57
User entered 'Yes (Y)'	Mia Rountree (b) (4)	14 Apr 2021 14:43:46
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:21:57
User entered '13 Apr 2021'	Mia Rountree (b) (4)	14 Apr 2021 14:43:46
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:21:57
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:46

US3912113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 14:43:46

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4)	14 Apr 2021 14:43:59
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4)	14 Apr 2021 14:43:59
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:18
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:48:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:43:59

US3912113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:25
User entered 'No (N)'	Mia Rountree (b) (4)	14 Apr 2021 14:44:04
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:48:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:25
User entered empty.	Mia Rountree (b) (4)	14 Apr 2021 14:44:04
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:31
User entered 'Yes (Y)'	Mia Rountree (b) (4)	14 Apr 2021 14:44:38
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:31
User entered '13 Apr 2021'	Mia Rountree (b) (4) (b) (4)	14 Apr 2021 14:44:38

US3912113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:31
User entered '14:58'	Mia Rountree (b) (4)	14 Apr 2021 14:44:38
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 14:58'	System	14 Apr 2021 14:44:38

US3912113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	14 Apr 2021 20:32:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:22:37
User entered 'Yes (Y)'	Mia Rountree (b) (4)	14 Apr 2021 14:44:44
	(b) (4)	

US3912113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:48:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 14:44:44

US3912113

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

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 21:53:08

US3912113

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

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:06
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 21:53:08

US3912113

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

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Mar 2021 21:53:08

US3912113

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

Form: Visit Date

Generated On: 12 Aug 2021 13:48:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 21:53:08

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:19:30
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
User entered '0'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 16:35:41
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:40:10

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 16:35:41
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:40:10

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:36:46
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User entered empty.	System	03 Mar 2021 21:54:37

US3912113

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

Form: Unblinding

Generated On: 12 Aug 2021 13:48:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User entered empty.	System	03 Mar 2021 21:54:37

US3912113

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 21:55:08

US3912113

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:00
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 21:55:08

US3912113

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:00
User entered '12:49'	(b) (4), (b) (6)	03 Mar 2021 21:55:08

US3912113

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User entered '3 Mar 2021 12:49'	System	03 Mar 2021 21:55:08

US3912113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:48:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 21:55:29

US3912113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:08
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 21:55:29

US3912113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:48:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:08
User entered '12:54'	(b) (4), (b) (6)	03 Mar 2021 21:55:29

US3912113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:42:34
User entered '3 Mar 2021 12:54'	System	03 Mar 2021 21:55:29

US3912113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:48:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	03 May 2021 17:50:52
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 17:41:47
Signature has been broken.	Sandra Clancy (b) (4)	03 May 2021 17:38:53
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Sandra Clancy (b) (4)	03 May 2021 17:38:53
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	03 May 2021 17:30:53
	(b) (4)	
DataPoint Un-verified.	Monique Gawlik (b) (4)	03 May 2021 15:54:02
Signature has been broken.	Monique Gawlik (b) (4)	03 May 2021 15:54:02
User entered 'Yes (Y)' reason for change: New Information	Monique Gawlik (b) (4)	03 May 2021 15:54:02
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:38:38
DataPoint Un-verified.	Mia Rountree (b) (4)	11 Jan 2021 22:58:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	11 Jan 2021 22:58:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:54:08
DataPoint Un-verified.	Mia Rountree (b) (4)	23 Oct 2020 21:26:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	23 Oct 2020 21:26:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 12:57:32
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Sep 2020 16:35:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Sep 2020 16:35:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Sep 2020 16:35:51
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Sep 2020 16:35:48

US3912113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:48:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Sep 2020 16:35:48
User entered 'No (N)'	(b) (4), (b) (6)	27 Sep 2020 16:35:38

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:14:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:07
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:51
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:21:48
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:21:43
Query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'medication taken on days 2 & 3 after dose 2. there is tylenol noted as starting 03Oct and is taken as needed. ' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:18:44

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'no medication taken on day 1 after dose 2' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:16:11
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'no medication taken per source' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:09:22
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:46:19
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:45:41
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:44:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

1683 of 1744

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:48:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 19:13:51
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:09:26

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:11:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:11:35
Data point term sent to Coder	System	08 Sep 2020 00:10:43
User entered 'Klonopin'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Anxiety'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered '0.5'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'un May 2019'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered '0'	Tina Rountree (b) (4)	08 Sep 2020 00:10:15
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:10:15

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:12:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 00:12:35
Data point term sent to Coder User entered 'Albuterol'	System Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:43 08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Asthma'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'I'	Tina Rountree (b) (4)	08 Sep 2020 00:11:17
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'puff (PUFF)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'un UNK 2001'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered '0'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:14:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 00:11:17

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 16:53:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:58:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 04:58:18
Data point term sent to Coder	System	09 Oct 2020 21:29:21
User entered 'Tylenol, Extra Strength, 500 mg tabs'	Sandra Clancy (b) (4)	09 Oct 2020 21:29:18
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 05:47:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' answered with 'confirming that the solicited event does not meet AE reporting criteria' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 18:08:38

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 08:51:06
	(b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'pain at the injection site'	Sandra Clancy (b) (4)	09 Oct 2020 21:29:18
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'I'	Sandra Clancy (b) (4)	09 Oct 2020 21:29:18
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'tablet (TABLET)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'as needed (PRN)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 13:53:58
User closed query 'Per CDM: Date format is not correctly recorded in Start date. Please review the Date field, it must be 2 digits(dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:54:05
Query 'Per CDM: Date format is not correctly recorded in Start date. Please review the Date field, it must be 2 digits(dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly. ' answered with 'updated' (Site from DM).	Tina Rountree (b) (4)	17 Oct 2020 22:49:02
	(b) (4)	
DataPoint Un-verified.	Tina Rountree (b) (4)	17 Oct 2020 22:48:54
	(b) (4)	
User entered '03 Oct 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	17 Oct 2020 22:48:54
	(b) (4)	
User opened query 'Per CDM: Date format is not correctly recorded in Start date. Please review the Date field, it must be 2 digits(dd-MMM-yyyy) format (e.g. 02-FEB-2019). Leading zeroes are acceptable, if applicable. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:06:00
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered '3 Oct 2020'	Sandra Clancy (b) (4)	09 Oct 2020 21:29:18
	(b) (4)	

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered '0'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:53:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:48:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:29:18

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:48:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:14:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:23
DataPoint Un-verified.	Monique Gawlik (b) (4)	10 Nov 2020 16:51:30
User entered 'Yes (Y)' reason for change: New Information	Monique Gawlik (b) (4)	10 Nov 2020 16:51:30
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:24:57
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	08 Sep 2020 00:11:36

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:48:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	18 Nov 2020 16:52:33
	(b) (4), (b) (6)	
User entered '6 Oct 2020'	Monique Gawlik (b) (4)	10 Nov 2020 16:52:32

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:48:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:52:33
User entered 'Upper Lower Endoscopy'	Monique Gawlik (b) (4)	10 Nov 2020 16:52:32

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:48:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
User closed query 'Per CDM: Please confirm if the underlying condition that led to this procedure is also captured in MH eCRF form and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:20:18
Query 'Per CDM: Please confirm if the underlying condition that led to this procedure is also captured in MH eCRF form and update as appropriate. Thank you.' answered with 'Procedure was preformed for purpose of nausea and weight loss, both captured in MH' (Site from DM).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 21:43:19
User opened query 'Per CDM: Please confirm if the underlying condition that led to this procedure is also captured in MH eCRF form and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 05:01:04
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:33
User entered 'Medical History (MH)'	Monique Gawlik (b) (4)	10 Nov 2020 16:52:32

US3912113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:48:45

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:20:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:33
User entered empty.	Monique Gawlik (b) (4)	10 Nov 2020 16:52:32