

US3722247 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:27:23

All time stamps listed in this document are displayed in GMT

US3722247

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

[Participant ID](#)

US3722247

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

US3722247

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 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

US3722247

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
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

US3722247

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input 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

US3722247

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3722247

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Were any significant conditions reported?

Yes ☒

No ☐

US3722247

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3722247

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3722247

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	17:56 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 17:56
Height (xxx.x)	69 in
Weight (xxx.x)	236.4 lb
BMI (xxx.x)	34.98317 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722247

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3722247

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Date of assessment (dd MMM yyyy) 13 AUG 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

US3722247

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 13 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3722247

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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

Visit date (dd MMM yyyy)	13 AUG 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
------------	--------

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 104050

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 ☒

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Height	ND - Not Done
Weight	ND - Not Done

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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)	13 AUG 2020
Time of assessment (00:00-23:59)	17:56 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 17:56
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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)	13 AUG 2020
Time of assessment (00:00-23:59)	18:56 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 18:56
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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.

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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) _____

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 18:26 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 18:26

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

US3722247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

18:17 (24 HR)

Collection date and time (derived)

13 AUG 2020 18:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:09	13 AUG 2020 18:09
Nasopharyngeal Swab 2	Yes	18:09	13 AUG 2020 18:09

US3722247

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

99.0 °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

13 AUG 2020 18:54

PC Open Date & Time

13 AUG 2020 18:46

PC Close Date & Time

13 AUG 2020 21:16

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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 96.4 °F

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

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

PC Time Stamp	14 AUG 2020 08:17
PC Open Date & Time	13 AUG 2020 22:11
PC Close Date & Time	14 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 00:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 AUG 2020 00:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:14

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

96.9 °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

17 AUG 2020 21:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

19 AUG 2020 08:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 22:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:56

PC Open Date & Time

13 AUG 2020 18:46

PC Close Date & Time

13 AUG 2020 21:16

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

14 AUG 2020 08:17

PC Open Date & Time

13 AUG 2020 22:11

PC Close Date & Time

14 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

15 AUG 2020 00:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

16 AUG 2020 00:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

17 AUG 2020 10:54

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

17 AUG 2020 21:59

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

19 AUG 2020 08:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

19 AUG 2020 22:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:55
PC Open Date & Time	13 AUG 2020 18:46
PC Close Date & Time	13 AUG 2020 21:16

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 08:18
PC Open Date & Time	13 AUG 2020 22:11
PC Close Date & Time	14 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 00:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 00:00
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 10:53
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:59
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 08:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:07
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3722247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:37

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:37

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:37

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:37

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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)	14 SEP 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 17:10
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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)	14 SEP 2020
Time of assessment (00:00-23:59)	18:08 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 18:08
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 17:33 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 17:33

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

US3722247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

17:29 (24 HR)

Collection date and time (derived)

14 SEP 2020 17:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:19	14 SEP 2020 17:19
Nasopharyngeal Swab 2	Yes	17:19	14 SEP 2020 17:19

US3722247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

98.4 °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

14 SEP 2020 18:02

PC Open Date & Time

14 SEP 2020 17:53

PC Close Date & Time

14 SEP 2020 20:23

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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 98.5 °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	14 SEP 2020 21:18
PC Open Date & Time	14 SEP 2020 21:18
PC Close Date & Time	15 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:04

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 09:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 10:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:45

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:21

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

98.6 °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

21 SEP 2020 08:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:01

PC Open Date & Time

14 SEP 2020 17:53

PC Close Date & Time

14 SEP 2020 20:23

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

1

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:19

PC Open Date & Time

14 SEP 2020 21:18

PC Close Date & Time

15 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

15 SEP 2020 12:06

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

17 SEP 2020 09:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

18 SEP 2020 10:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

18 SEP 2020 12:44

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

19 SEP 2020 20:20

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

21 SEP 2020 08:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 18:01
PC Open Date & Time	14 SEP 2020 17:53
PC Close Date & Time	14 SEP 2020 20:23

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 21:20
PC Open Date & Time	14 SEP 2020 21:18
PC Close Date & Time	15 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:03
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 09:35
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 10:51
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:45
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

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 ☒

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 08:20
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3722247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 17:21
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3722247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

17:21 (24 HR)

Collection date and time (derived)

16 OCT 2020 17:21

US3722247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

20 OCT 2020 15:09:32

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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"/>

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 92
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"/>

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 99
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"/>

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

23 NOV 2020 17:16:11

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 10:48:18

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

09 DEC 2020 10:23:36

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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	12 DEC 2020 12:02:27
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 12:25:32

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

26 DEC 2020 08:05:01

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

04 JAN 2021 12:06:05

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

09 JAN 2021 16:31:42

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 10:48:39

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

26 JAN 2021 12:28:50

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

31 JAN 2021 15:23:15

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 17:38:15

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 22:34:44

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 10:14:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

28 FEB 2021 08:54:51

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

08 MAR 2021 17:51:55

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

13 MAR 2021 08:50:10

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

20 MAR 2021 08:20:12

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

29 MAR 2021 11:53:46

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

03 APR 2021 10:17:21

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 15:37:01

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

Date and time of submission

20 APR 2021 16:52:30

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:56:55

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

Patient Cloud Close Date & Time	18 AUG 2021 23:59
---	-------------------

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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°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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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 ☐
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 ☐

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3722247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:27:23

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		28 FEB 2021 08:54:40

US3722247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:27:58

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:27:38

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

SEVERAL ATTEMPTS HAVE
BEEN MADE TO CONTACT
SUBJECT FOR SITE CALL VISIT
BUT HAVE NOT BEEN
SUCCESSFUL WITH REACHING
PATIENT OR RECEIVED A CALL
BACK.

US3722247

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

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

Visit date (dd MMM yyyy)	4 MAR 2021
--------------------------	------------

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

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

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 16:06
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722247

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3722247

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	16:25 (24 HR)
Collection date and time (derived)	4 MAR 2021 16:25

US3722247

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:27:36

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

US3722247

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722247

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:27:23

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"/>

US3722247

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:27:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722247

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 FEB 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

US3722247

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Date of updated informed consent (<i>dd MMM yyyy</i>)	1 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	1 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3722247

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Height	
Weight	
BMI (xxx.x)	

US3722247

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Height	
Weight	
BMI (xxx.x)	
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)	1 FEB 2021
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 16:55
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:54:10

Generated On: 12 Aug 2021 13:27:23

Height	
Weight	
BMI (xxx.x)	
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)	1 FEB 2021
Time of assessment (00:00-23:59)	17:36 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 17:36
Temperature (xxx.x)	98.4 F
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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 FEB 2021

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

US3722247

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

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	1 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3722247

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 1 FEB 2021

What was the treatment time? (00:00-23:59) 17:04 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 17:04

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

US3722247

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	16:50 (24 HR)
Collection date and time (derived)	1 FEB 2021 16:50

US3722247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	16:52
Collection Date and Time (derived)	1 FEB 2021 16:52

US3722247

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3722247

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	OLD29

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 16:06
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	17:14 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 17:14
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722247

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	4 MAR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3722247

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 4 MAR 2021

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 4 MAR 2021 16:44

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

US3722247

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722247

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:54:11

Generated On: 12 Aug 2021 13:27:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722247

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	OLD57

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 11:50
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722247

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

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.

US3722247

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

11:55 (24 HR)

Collection date and time (derived)

12 APR 2021 11:55

US3722247

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

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

Yes ☒

No ☐

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

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

352 of 1901

EAB) (1725)

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

	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 DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Name of Medication TRETINOIN 0.25%

Prophylaxis Yes ☐
No ☒

Indication ACNE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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)

354 of 1901

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

	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 DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:54:08

Generated On: 12 Aug 2021 13:27:23

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3722247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:27:23

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3722247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:27:23

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

US3722247 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722247

Form: Participant Creation

Generated On: 12 Aug 2021 13:27:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'US3722247'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:44:13

US3722247

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:34:37

US3722247

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:44:14

US3722247

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Clinic (Clinic)'	Taylor Wilson (b) (4)	13 Aug 2020 22:34:37

US3722247

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'SCRN'	System	13 Aug 2020 22:34:37

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered (b) (6) 1996'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:44:15

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '24'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'YEARS'	System	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '24'	System	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Female (F)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'I'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:27:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:00

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '13 Aug 2020'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Aug 2020'	System	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2020'	System	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 12:26:49
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:17:49
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:17:45
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:43:13
User entered 'Amendment 5 (5)'	Taylor Wilson (b) (4) (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:13

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:44:14

US3722247

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:27:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'I'	System	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:27:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:46

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 12:31:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 12:31:18
Data point term sent to Coder	System	14 Aug 2020 12:29:58
User entered 'hypothyroidism'	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'un Dec 2018'	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Dec 2018'	System	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2018'	System	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered empty.	System	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered empty.	System	14 Aug 2020 12:29:04

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 12:31:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 12:31:18
Data point term sent to Coder	System	14 Aug 2020 12:29:58
User entered 'acne'	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'un UNK 2015'	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Jan 2015'	System	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2015'	System	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered empty.	System	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered empty.	System	14 Aug 2020 12:29:20

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User closed query 'Per MM, please review and update the term to final diagnosis ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:33:11
Query 'Per MM, please review and update the term to final diagnosis ' answered with 'Subject stated that snoring is final diagnosis and subject denied being diagnosed with sleep apnea' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Sep 2020 15:28:57
User opened query 'Per MM, please review and update the term to final diagnosis ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:06:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Snoring, LLT: Snoring - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:31:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:31:18
Data point term sent to Coder	System	14 Aug 2020 12:29:58
User entered 'snoring'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'un UNK 2000'	Kayla Peay (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'un UNK 2000'	Kayla Peay (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Jan 2000'	System	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2000'	System	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Jan 2000'	System	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2000'	System	14 Aug 2020 12:29:37

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 19:14:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 19:14:49
Data point term sent to Coder	System	22 Mar 2021 19:14:08
User entered 'tonsillitis'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'un UNK 2001'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '0'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'No (N)'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'un UNK 2001'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '0'	Marlee Smith (b) (4)	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Jan 2001'	System	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2001'	System	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'Jan 2001'	System	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '2001'	System	22 Mar 2021 19:13:25

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '17:56'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered '13 Aug 2020 17:56'	System	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '69' in	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
DataPoint set to visible.	System	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '236.4' lb	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
DataPoint set to visible.	System	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
Amendment Manager: User entered '34.98317'	System	16 Sep 2020 23:56:28
User entered '35.0'	System	14 Aug 2020 12:30:29
DataPoint set to visible.	System	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'kg/m2'	System	14 Aug 2020 12:30:29
DataPoint set to visible.	System	13 Aug 2020 22:35:23

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:15
User entered '98.1' F	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
	(b) (4)	

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:27:15
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:15
User entered '78'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
	(b) (4)	

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'bpm'	System	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:15
User entered '17'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
	(b) (4)	

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'breaths/min'	System	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:15
User entered '116'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
	(b) (4)	

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'mmHg'	System	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:15
User entered '74'	Kayla Peay (b) (4)	14 Aug 2020 12:30:29
	(b) (4)	

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered 'mmHg'	System	14 Aug 2020 12:30:29

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59

US3722247

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59

US3722247

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:40

US3722247

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 20:10:16
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 21:37:16
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:30:40

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:27:23

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:30:48

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User entered empty.	System	14 Aug 2020 12:30:59

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'I'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '0'	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:27:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:28:59
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:35:58

US3722247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:16

US3722247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:16

US3722247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Clinic (Clinic)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:16

US3722247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'VISIT1'	System	13 Aug 2020 22:36:16

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:31

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:23:34
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:23:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 21:54:31
User entered '104050' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:31

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:31

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

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)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:33

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

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)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:33

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:33

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:33

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Taylor Wilson (b) (4)	13 Aug 2020 22:36:33

US3722247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:27:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:36:35
Query 'per CDM: please input yes or no in this field' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	21 Dec 2020 20:24:21
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	21 Dec 2020 20:24:17
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:57:14
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:11:22

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '69' in	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '236.4' lb	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '69' in	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '236.4' lb	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:56'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 17:56'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '98.1' F	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '78'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'bpm'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'breaths/min'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '116'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '74'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '69' in	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 19:27:23
User entered '236.4' lb	Kayla Peay (b) (4)	14 Aug 2020 12:32:34
	(b) (4)	

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 11:09:44
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 12:32:34
User entered '18:56'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 18:56'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '99' F	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '73'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'bpm'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'breaths/min'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '106'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '72'	Kayla Peay (b) (4)	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	14 Aug 2020 12:32:34

US3722247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:27:30
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:40

US3722247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:27:30
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:32:40

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 12:41:55
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'updated' (Site from DM).	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:44:39
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:44:34
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:21:29
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 19:44:34
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 19:44:34
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 19:44:34
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:08:28
Query 'per CDM: please select yes or no for this field' answered with 'Completed ' (Site from DM).	Sara Poff (b) (4) (b) (4)	05 Nov 2020 21:56:59
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	05 Nov 2020 21:56:44
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:29:50
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 19:44:34
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered empty.	System	14 Aug 2020 12:32:48

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 22:39:28
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	13 Aug 2020 22:39:28
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	13 Aug 2020 22:37:36
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18:26'	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 18:26'	System	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Taylor Wilson (b) (4)	13 Aug 2020 22:39:28
User entered empty.	Taylor Wilson (b) (4)	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'ONCE'	System	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 22:37:36

US3722247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:33:04

US3722247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:33:04

US3722247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18:17'	Kayla Peay (b) (4)	14 Aug 2020 12:33:04

US3722247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 18:17'	System	14 Aug 2020 12:33:04

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:27:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '13 Aug 2020'	Kayla Peay (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18:09'	Kayla Peay (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 18:09'	System	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18:09'	Kayla Peay (b) (4)	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '13 Aug 2020 18:09'	System	14 Aug 2020 12:33:17

US3722247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:26:24

US3722247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	14 Aug 2020 12:26:24

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:54:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac9009bb-511c-46e2-961c-f6f8e4078246'	System	13 Aug 2020 22:54:51
User entered 'Yes (Y)'	System	13 Aug 2020 22:54:51

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:54:39', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac9009bb-511c-46e2-961c-f6f8e4078246'	System	13 Aug 2020 22:54:51
User entered '99.0'	System	13 Aug 2020 22:54:51

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:54:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac9009bb-511c-46e2-961c-f6f8e4078246'	System	13 Aug 2020 22:54:51
User entered 'No (N)'	System	13 Aug 2020 22:54:51

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:54:47', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac9009bb-511c-46e2-961c-f6f8e4078246'	System	13 Aug 2020 22:54:51
User entered '13 Aug 2020 18:54'	System	13 Aug 2020 22:54:51

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 18:46'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 21:16'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:34', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b63c142d-422a-4569-8869-5613a6d461c3'	System	14 Aug 2020 12:17:50
User entered 'Yes (Y)'	System	14 Aug 2020 12:17:50

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:39', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b63c142d-422a-4569-8869-5613a6d461c3'	System	14 Aug 2020 12:17:50
User entered '96.4'	System	14 Aug 2020 12:17:50

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b63c142d-422a-4569-8869-5613a6d461c3'	System	14 Aug 2020 12:17:50
User entered 'No (N)'	System	14 Aug 2020 12:17:50

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:45', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b63c142d-422a-4569-8869-5613a6d461c3'	System	14 Aug 2020 12:17:50
User entered '14 Aug 2020 08:17'	System	14 Aug 2020 12:17:50

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 22:11'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 2'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'af21ae2e-6bea-4635-a6ca-bf89564ca3ba'	System	15 Aug 2020 04:02:12
User entered 'Yes (Y)'	System	15 Aug 2020 04:02:12

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:02:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'af21ae2e-6bea-4635-a6ca-bf89564ca3ba'	System	15 Aug 2020 04:02:12
User entered '97.9'	System	15 Aug 2020 04:02:12

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:02:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'af21ae2e-6bea-4635-a6ca-bf89564ca3ba'	System	15 Aug 2020 04:02:12
User entered 'No (N)'	System	15 Aug 2020 04:02:12

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:02:06', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'af21ae2e-6bea-4635-a6ca-bf89564ca3ba'	System	15 Aug 2020 04:02:12
User entered '15 Aug 2020 00:02'	System	15 Aug 2020 04:02:12

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 3'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	System	16 Aug 2020 04:01:38
User entered 'Yes (Y)'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	System	16 Aug 2020 04:01:38
User entered '97.9'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:01:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	System	16 Aug 2020 04:01:38
User entered 'Yes (Y)'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
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 'confirmed' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 14:28:34
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 (4bdf1659668cb742)', Time: '2020-08-16T00:01:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	Amy Ford (b) (4)	17 Aug 2020 17:15:39
User entered '1'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:01:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	System	16 Aug 2020 04:01:38
User entered '0'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:01:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '49260667-3df8-4bb2-8ff3-10a1e77b67c5'	System	16 Aug 2020 04:01:38
User entered '16 Aug 2020 00:01'	System	16 Aug 2020 04:01:38

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 4'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T22:14:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '185bb427-3f23-427f-af5f-c3b003d59fe0'	System	17 Aug 2020 02:14:27
User entered 'Yes (Y)'	System	17 Aug 2020 02:14:27

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T22:14:19', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '185bb427-3f23-427f-af5f-c3b003d59fe0'	System	17 Aug 2020 02:14:27
User entered '98.3'	System	17 Aug 2020 02:14:27

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T22:14:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '185bb427-3f23-427f-af5f-c3b003d59fe0'	System	17 Aug 2020 02:14:27
User entered 'No (N)'	System	17 Aug 2020 02:14:27

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T22:14:24', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '185bb427-3f23-427f-af5f-c3b003d59fe0'	System	17 Aug 2020 02:14:27
User entered '16 Aug 2020 22:14'	System	17 Aug 2020 02:14:27

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 5'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:58:50', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6dbbc3ab-79a8-4407-95d1-7eb052c45c64'	System	18 Aug 2020 01:59:08
User entered 'Yes (Y)'	System	18 Aug 2020 01:59:08

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:58:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6dbbc3ab-79a8-4407-95d1-7eb052c45c64'	System	18 Aug 2020 01:59:08
User entered '96.9'	System	18 Aug 2020 01:59:08

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:58:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6dbbc3ab-79a8-4407-95d1-7eb052c45c64'	System	18 Aug 2020 01:59:08
User entered 'No (N)'	System	18 Aug 2020 01:59:08

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:02', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6dbbc3ab-79a8-4407-95d1-7eb052c45c64'	System	18 Aug 2020 01:59:08
User entered '17 Aug 2020 21:59'	System	18 Aug 2020 01:59:08

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 6'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2b9b2076-678f-4db5-a9d2-2f56befd40fc'	System	19 Aug 2020 12:56:26
User entered 'Yes (Y)'	System	19 Aug 2020 12:56:26

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:16', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2b9b2076-678f-4db5-a9d2-2f56befd40fc'	System	19 Aug 2020 12:56:26
User entered '97.6'	System	19 Aug 2020 12:56:26

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:18', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2b9b2076-678f-4db5-a9d2-2f56befd40fc'	System	19 Aug 2020 12:56:26
User entered 'No (N)'	System	19 Aug 2020 12:56:26

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2b9b2076-678f-4db5-a9d2-2f56befd40fc'	System	19 Aug 2020 12:56:26
User entered '19 Aug 2020 08:56'	System	19 Aug 2020 12:56:26

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 7'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:06:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '486926bb-4c1a-4a7c-b98e-5c247ff17a74'	System	20 Aug 2020 02:06:59
User entered 'Yes (Y)'	System	20 Aug 2020 02:06:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:06:46', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '486926bb-4c1a-4a7c-b98e-5c247ff17a74'	System	20 Aug 2020 02:06:59
User entered '98.1'	System	20 Aug 2020 02:06:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:06:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '486926bb-4c1a-4a7c-b98e-5c247ff17a74'	System	20 Aug 2020 02:06:59
User entered 'No (N)'	System	20 Aug 2020 02:06:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:06:51', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '486926bb-4c1a-4a7c-b98e-5c247ff17a74'	System	20 Aug 2020 02:06:59
User entered '19 Aug 2020 22:06'	System	20 Aug 2020 02:06:59

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2a1bbe4c-8813-4cac-9d3d-60a7dffffdbf'	System	13 Aug 2020 22:56:12
User entered 'None (1)'	System	13 Aug 2020 22:56:12

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:55', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2a1bbe4c-8813-4cac-9d3d-60a7dffffdbf'	System	13 Aug 2020 22:56:12
User entered 'No (N)'	System	13 Aug 2020 22:56:12

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2a1bbe4c-8813-4cac-9d3d-60a7dffffdbf'	System	13 Aug 2020 22:56:12
User entered 'No (N)'	System	13 Aug 2020 22:56:12

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:56:04', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2a1bbe4c-8813-4cac-9d3d-60a7dffffdbf'	System	13 Aug 2020 22:56:12
User entered 'None (1)'	System	13 Aug 2020 22:56:12

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:56:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2a1bbe4c-8813-4cac-9d3d-60a7dffffdbf'	System	13 Aug 2020 22:56:12
User entered '13 Aug 2020 18:56'	System	13 Aug 2020 22:56:12

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 18:46'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 21:16'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:16:57', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '78a170e3-a163-4bfe-85e0-1119c5da544e'	System	14 Aug 2020 12:17:32
User entered 'None (1)'	System	14 Aug 2020 12:17:32

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '78a170e3-a163-4bfe-85e0-1119c5da544e'	System	14 Aug 2020 12:17:32
User entered 'No (N)'	System	14 Aug 2020 12:17:32

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '78a170e3-a163-4bfe-85e0-1119c5da544e'	System	14 Aug 2020 12:17:32
User entered 'No (N)'	System	14 Aug 2020 12:17:32

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '78a170e3-a163-4bfe-85e0-1119c5da544e'	System	14 Aug 2020 12:17:32
User entered 'None (1)'	System	14 Aug 2020 12:17:32

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '78a170e3-a163-4bfe-85e0-1119c5da544e'	System	14 Aug 2020 12:17:32
User entered '14 Aug 2020 08:17'	System	14 Aug 2020 12:17:32

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 22:11'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 2'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:20', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9aaf8707-cfd5-4ba0-beee-025f6d3cd14d'	System	15 Aug 2020 04:00:42
User entered 'None (1)'	System	15 Aug 2020 04:00:42

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:22', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9aaf8707-cfd5-4ba0-beee-025f6d3cd14d'	System	15 Aug 2020 04:00:42
User entered 'No (N)'	System	15 Aug 2020 04:00:42

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9aaf8707-cfd5-4ba0-beee-025f6d3cd14d'	System	15 Aug 2020 04:00:42
User entered 'No (N)'	System	15 Aug 2020 04:00:42

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9aaf8707-cfd5-4ba0-beee-025f6d3cd14d'	System	15 Aug 2020 04:00:42
User entered 'None (1)'	System	15 Aug 2020 04:00:42

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9aaf8707-cfd5-4ba0-beee-025f6d3cd14d'	System	15 Aug 2020 04:00:42
User entered '15 Aug 2020 00:00'	System	15 Aug 2020 04:00:42

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 3'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:27', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '355392d9-a3e7-426b-88a9-a2167123d249'	System	16 Aug 2020 04:00:43
User entered 'None (1)'	System	16 Aug 2020 04:00:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '355392d9-a3e7-426b-88a9-a2167123d249'	System	16 Aug 2020 04:00:43
User entered 'No (N)'	System	16 Aug 2020 04:00:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '355392d9-a3e7-426b-88a9-a2167123d249'	System	16 Aug 2020 04:00:43
User entered 'No (N)'	System	16 Aug 2020 04:00:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '355392d9-a3e7-426b-88a9-a2167123d249'	System	16 Aug 2020 04:00:43
User entered 'None (1)'	System	16 Aug 2020 04:00:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '355392d9-a3e7-426b-88a9-a2167123d249'	System	16 Aug 2020 04:00:43
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 4'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:53', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a3143ada-d8e2-45f4-ac35-95ef74b87b43'	System	17 Aug 2020 14:54:14
User entered 'None (1)'	System	17 Aug 2020 14:54:14

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a3143ada-d8e2-45f4-ac35-95ef74b87b43'	System	17 Aug 2020 14:54:14
User entered 'No (N)'	System	17 Aug 2020 14:54:14

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a3143ada-d8e2-45f4-ac35-95ef74b87b43'	System	17 Aug 2020 14:54:14
User entered 'No (N)'	System	17 Aug 2020 14:54:14

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a3143ada-d8e2-45f4-ac35-95ef74b87b43'	System	17 Aug 2020 14:54:14
User entered 'None (1)'	System	17 Aug 2020 14:54:14

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:54:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a3143ada-d8e2-45f4-ac35-95ef74b87b43'	System	17 Aug 2020 14:54:14
User entered '17 Aug 2020 10:54'	System	17 Aug 2020 14:54:14

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 5'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '57c829bf-363d-4e86-bbbc-8b15e1896ae0'	System	18 Aug 2020 01:59:26
User entered 'None (1)'	System	18 Aug 2020 01:59:26

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '57c829bf-363d-4e86-bbbc-8b15e1896ae0'	System	18 Aug 2020 01:59:26
User entered 'No (N)'	System	18 Aug 2020 01:59:26

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:14', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '57c829bf-363d-4e86-bbbc-8b15e1896ae0'	System	18 Aug 2020 01:59:26
User entered 'No (N)'	System	18 Aug 2020 01:59:26

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:17', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '57c829bf-363d-4e86-bbbc-8b15e1896ae0'	System	18 Aug 2020 01:59:26
User entered 'None (1)'	System	18 Aug 2020 01:59:26

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:19', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '57c829bf-363d-4e86-bbbc-8b15e1896ae0'	System	18 Aug 2020 01:59:26
User entered '17 Aug 2020 21:59'	System	18 Aug 2020 01:59:26

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 6'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ab66115a-fab1-4b62-a136-82c7b06a78e5'	System	19 Aug 2020 12:56:43
User entered 'None (1)'	System	19 Aug 2020 12:56:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ab66115a-fab1-4b62-a136-82c7b06a78e5'	System	19 Aug 2020 12:56:43
User entered 'No (N)'	System	19 Aug 2020 12:56:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ab66115a-fab1-4b62-a136-82c7b06a78e5'	System	19 Aug 2020 12:56:43
User entered 'No (N)'	System	19 Aug 2020 12:56:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ab66115a-fab1-4b62-a136-82c7b06a78e5'	System	19 Aug 2020 12:56:43
User entered 'None (1)'	System	19 Aug 2020 12:56:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ab66115a-fab1-4b62-a136-82c7b06a78e5'	System	19 Aug 2020 12:56:43
User entered '19 Aug 2020 08:56'	System	19 Aug 2020 12:56:43

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 7'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a216099e-e5f3-4fe9-9f45-1007cdad0351'	System	20 Aug 2020 02:07:38
User entered 'None (1)'	System	20 Aug 2020 02:07:38

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a216099e-e5f3-4fe9-9f45-1007cdad0351'	System	20 Aug 2020 02:07:38
User entered 'No (N)'	System	20 Aug 2020 02:07:38

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:25', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a216099e-e5f3-4fe9-9f45-1007cdad0351'	System	20 Aug 2020 02:07:38
User entered 'No (N)'	System	20 Aug 2020 02:07:38

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a216099e-e5f3-4fe9-9f45-1007cdad0351'	System	20 Aug 2020 02:07:38
User entered 'None (1)'	System	20 Aug 2020 02:07:38

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a216099e-e5f3-4fe9-9f45-1007cdad0351'	System	20 Aug 2020 02:07:38
User entered '19 Aug 2020 22:07'	System	20 Aug 2020 02:07:38

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'None (0)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'No interference with activity (1)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'None (0)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:25', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'None (0)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:27', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'None (0)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'None (0)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:36', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered 'No (N)'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-13T18:55:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '03acf984-2537-4a4d-8d47-88241e5e4a26'	System	13 Aug 2020 22:55:41
User entered '13 Aug 2020 18:55'	System	13 Aug 2020 22:55:41

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 18:46'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 21:16'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:50', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:52', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:17:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:18:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'None (0)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:18:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered 'No (N)'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T08:18:09', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb5ca9d3-3e00-4776-a4ae-dc250a58a8b5'	System	14 Aug 2020 12:18:13
User entered '14 Aug 2020 08:18'	System	14 Aug 2020 12:18:13

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '13 Aug 2020 22:11'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 2'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-14T23:59:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'None (0)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered 'No (N)'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-15T00:00:15', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '8d4a2c35-125b-4e88-8ed1-1ba68aec3d53'	System	15 Aug 2020 04:00:22
User entered '15 Aug 2020 00:00'	System	15 Aug 2020 04:00:22

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 3'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:04', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:09', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:11', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'None (0)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:19', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered 'No (N)'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-16T00:00:22', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'cc304fea-ae4f-4e62-9d76-e0f18e23e9ce'	System	16 Aug 2020 04:00:29
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:29

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 4'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'None (0)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:46', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered 'No (N)'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T10:53:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '59057015-dae5-471e-b820-514a9878b377'	System	17 Aug 2020 14:53:54
User entered '17 Aug 2020 10:53'	System	17 Aug 2020 14:53:54

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 5'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:25', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:27', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'None (0)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered 'No (N)'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-17T21:59:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b19855c5-94b5-4f90-a4c6-a14cda036bcb'	System	18 Aug 2020 01:59:42
User entered '17 Aug 2020 21:59'	System	18 Aug 2020 01:59:42

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 6'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:43', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:45', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:47', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'None (0)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered 'No (N)'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T08:56:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '32b38441-50a3-470c-8ecf-473a84213256'	System	19 Aug 2020 12:57:05
User entered '19 Aug 2020 08:56'	System	19 Aug 2020 12:57:05

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 7'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:06', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:09', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:11', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'None (0)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:14', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered 'No (N)'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-08-19T22:07:17', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6c480fd6-4de7-4bc5-a3c8-3808cf519a9e'	System	20 Aug 2020 02:07:24
User entered '19 Aug 2020 22:07'	System	20 Aug 2020 02:07:24

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:37:36

US3722247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Amy Ford (b) (4)	23 Aug 2020 19:19:13

US3722247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '23 Aug 2020'	Amy Ford (b) (4)	23 Aug 2020 19:19:13

US3722247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	23 Aug 2020 19:19:13

US3722247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Amy Ford (b) (4)	23 Aug 2020 19:19:13

US3722247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Amy Ford (b) (4)	23 Aug 2020 19:19:18

US3722247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	23 Aug 2020 19:19:18

US3722247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 14:03:11

US3722247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '29 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 14:03:11

US3722247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	31 Aug 2020 14:03:11

US3722247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 14:03:11

US3722247

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 14:03:14

US3722247

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	31 Aug 2020 14:03:14

US3722247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Amy Ford (b) (4)	06 Sep 2020 23:48:04

US3722247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '6 Sep 2020'	Amy Ford (b) (4)	06 Sep 2020 23:48:04

US3722247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	06 Sep 2020 23:48:04

US3722247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Amy Ford (b) (4)	06 Sep 2020 23:48:04

US3722247

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Amy Ford (b) (4)	06 Sep 2020 23:48:09

US3722247

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	06 Sep 2020 23:48:09

US3722247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	14 Sep 2020 21:37:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Sara Poff (b) (4)	14 Sep 2020 21:37:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	14 Sep 2020 21:37:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'VISIT2'	System	14 Sep 2020 21:37:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:10'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 17:10'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '98.9' F	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '78'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'bpm'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'breaths/min'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '128'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '87'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '18:08'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 18:08'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '98.4' F	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '73'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'bpm'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '15'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'breaths/min'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '111'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '83'	Kayla Peay (b) (4)	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	15 Sep 2020 12:43:29

US3722247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:41

US3722247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:43:41

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'No (N)'	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered empty.	System	15 Sep 2020 12:43:48

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:33'	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 17:33'	System	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'ONCE'	System	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 21:37:34

US3722247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:44:03

US3722247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:44:03

US3722247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:29'	Kayla Peay (b) (4)	15 Sep 2020 12:44:03

US3722247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 17:29'	System	15 Sep 2020 12:44:03

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:27:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '14 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:19'	Kayla Peay (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 17:19'	System	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:19'	Kayla Peay (b) (4)	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '14 Sep 2020 17:19'	System	15 Sep 2020 12:44:16

US3722247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	14 Sep 2020 21:37:41

US3722247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '1'	System	14 Sep 2020 21:37:41

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac04b127-240b-45fb-8c6b-dd4cbd3ef0b0'	System	14 Sep 2020 22:02:39
User entered 'Yes (Y)'	System	14 Sep 2020 22:02:39

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:02:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac04b127-240b-45fb-8c6b-dd4cbd3ef0b0'	System	14 Sep 2020 22:02:39
User entered '98.4'	System	14 Sep 2020 22:02:39

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:02:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac04b127-240b-45fb-8c6b-dd4cbd3ef0b0'	System	14 Sep 2020 22:02:39
User entered 'No (N)'	System	14 Sep 2020 22:02:39

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:02:15', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac04b127-240b-45fb-8c6b-dd4cbd3ef0b0'	System	14 Sep 2020 22:02:39
User entered '14 Sep 2020 18:02'	System	14 Sep 2020 22:02:39

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 17:53'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 20:23'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '660ba6ec-3ee1-4ab0-af2c-b01a7ed01287'	System	15 Sep 2020 01:18:56
User entered 'Yes (Y)'	System	15 Sep 2020 01:18:56

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '660ba6ec-3ee1-4ab0-af2c-b01a7ed01287' User entered '98.5'	System	15 Sep 2020 01:18:56
	System	15 Sep 2020 01:18:56

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:47', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '660ba6ec-3ee1-4ab0-af2c-b01a7ed01287'	System	15 Sep 2020 01:18:56
User entered 'No (N)'	System	15 Sep 2020 01:18:56

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '660ba6ec-3ee1-4ab0-af2c-b01a7ed01287'	System	15 Sep 2020 01:18:56
User entered '14 Sep 2020 21:18'	System	15 Sep 2020 01:18:56

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 21:18'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 2'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:04:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '30d3b5c6-beae-4079-a1d4-5a3aeb1b6afc'	System	15 Sep 2020 16:05:52
User entered 'Yes (Y)'	System	15 Sep 2020 16:05:52

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:04:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '30d3b5c6-beae-4079-a1d4-5a3aeb1b6afc'	System	15 Sep 2020 16:05:52
User entered '98.3'	System	15 Sep 2020 16:05:52

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:04:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '30d3b5c6-beae-4079-a1d4-5a3aeb1b6afc'	System	15 Sep 2020 16:05:52
User entered 'No (N)'	System	15 Sep 2020 16:05:52

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:04:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '30d3b5c6-beae-4079-a1d4-5a3aeb1b6afc'	System	15 Sep 2020 16:05:52
User entered '15 Sep 2020 12:04'	System	15 Sep 2020 16:05:52

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 3'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'bd53c401-8b6d-4f16-a103-1d95735fa324'	System	17 Sep 2020 13:35:02
User entered 'Yes (Y)'	System	17 Sep 2020 13:35:02

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'bd53c401-8b6d-4f16-a103-1d95735fa324'	System	17 Sep 2020 13:35:02
User entered '97.4'	System	17 Sep 2020 13:35:02

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:51', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'bd53c401-8b6d-4f16-a103-1d95735fa324'	System	17 Sep 2020 13:35:02
User entered 'No (N)'	System	17 Sep 2020 13:35:02

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:53', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'bd53c401-8b6d-4f16-a103-1d95735fa324'	System	17 Sep 2020 13:35:02
User entered '17 Sep 2020 09:34'	System	17 Sep 2020 13:35:02

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 4'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0a87d622-e17f-493e-88a3-cb05348e4e33'	System	18 Sep 2020 14:51:35
User entered 'Yes (Y)'	System	18 Sep 2020 14:51:35

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:17', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0a87d622-e17f-493e-88a3-cb05348e4e33'	System	18 Sep 2020 14:51:35
User entered '98.3'	System	18 Sep 2020 14:51:35

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0a87d622-e17f-493e-88a3-cb05348e4e33'	System	18 Sep 2020 14:51:35
User entered 'No (N)'	System	18 Sep 2020 14:51:35

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0a87d622-e17f-493e-88a3-cb05348e4e33'	System	18 Sep 2020 14:51:35
User entered '18 Sep 2020 10:51'	System	18 Sep 2020 14:51:35

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 5'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9d47b4bc-4590-43b4-a037-704a40a2030e'	System	18 Sep 2020 16:45:44
User entered 'Yes (Y)'	System	18 Sep 2020 16:45:44

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9d47b4bc-4590-43b4-a037-704a40a2030e' User entered '98.1'	System	18 Sep 2020 16:45:44
	System	18 Sep 2020 16:45:44

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:34', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9d47b4bc-4590-43b4-a037-704a40a2030e'	System	18 Sep 2020 16:45:44
User entered 'No (N)'	System	18 Sep 2020 16:45:44

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9d47b4bc-4590-43b4-a037-704a40a2030e' User entered '18 Sep 2020 12:45'	System	18 Sep 2020 16:45:44
	System	18 Sep 2020 16:45:44

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 6'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '74589aa1-c85a-4c22-b28a-a8fd484c5b40'	System	20 Sep 2020 00:22:00
User entered 'Yes (Y)'	System	20 Sep 2020 00:22:00

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '74589aa1-c85a-4c22-b28a-a8fd484c5b40'	System	20 Sep 2020 00:22:00
User entered '97.7'	System	20 Sep 2020 00:22:00

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '74589aa1-c85a-4c22-b28a-a8fd484c5b40'	System	20 Sep 2020 00:22:00
User entered 'No (N)'	System	20 Sep 2020 00:22:00

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:45', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '74589aa1-c85a-4c22-b28a-a8fd484c5b40'	System	20 Sep 2020 00:22:00
User entered '19 Sep 2020 20:21'	System	20 Sep 2020 00:22:00

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 7'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:18', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '1a5131e6-dcc8-4113-98a9-64e2fdeacea8'	System	21 Sep 2020 12:20:49
User entered 'Yes (Y)'	System	21 Sep 2020 12:20:49

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '1a5131e6-dcc8-4113-98a9-64e2fdeacea8'	System	21 Sep 2020 12:20:49
User entered '98.6'	System	21 Sep 2020 12:20:49

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:43', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '1a5131e6-dcc8-4113-98a9-64e2fdeacea8'	System	21 Sep 2020 12:20:49
User entered 'No (N)'	System	21 Sep 2020 12:20:49

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:45', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '1a5131e6-dcc8-4113-98a9-64e2fdeacea8'	System	21 Sep 2020 12:20:49
User entered '21 Sep 2020 08:20'	System	21 Sep 2020 12:20:49

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:00:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '86df4c79-e8fa-4ee7-9ec9-93955c753797'	System	14 Sep 2020 22:02:08
User entered 'None (1)'	System	14 Sep 2020 22:02:08

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:00:41', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '86df4c79-e8fa-4ee7-9ec9-93955c753797'	System	14 Sep 2020 22:02:08
User entered 'No (N)'	System	14 Sep 2020 22:02:08

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:00:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '86df4c79-e8fa-4ee7-9ec9-93955c753797'	System	14 Sep 2020 22:02:08
User entered 'No (N)'	System	14 Sep 2020 22:02:08

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '86df4c79-e8fa-4ee7-9ec9-93955c753797'	System	14 Sep 2020 22:02:08
User entered 'None (1)'	System	14 Sep 2020 22:02:08

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:04', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '86df4c79-e8fa-4ee7-9ec9-93955c753797'	System	14 Sep 2020 22:02:08
User entered '14 Sep 2020 18:01'	System	14 Sep 2020 22:02:08

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 17:53'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 20:23'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:55', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered 'None (1)'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:18:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered 'No (N)'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered 'Yes (Y)'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered '1'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:41', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered 'None (1)'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:43', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b31314f-23fd-4e30-8752-b3846da2d561'	System	15 Sep 2020 01:19:51
User entered '14 Sep 2020 21:19'	System	15 Sep 2020 01:19:51

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 21:18'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 2'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:05:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f7be1c0d-d523-449c-b337-1408bad02dad'	System	15 Sep 2020 16:07:11
User entered 'None (1)'	System	15 Sep 2020 16:07:11

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:05:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f7be1c0d-d523-449c-b337-1408bad02dad'	System	15 Sep 2020 16:07:11
User entered 'No (N)'	System	15 Sep 2020 16:07:11

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:05:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f7be1c0d-d523-449c-b337-1408bad02dad'	System	15 Sep 2020 16:07:11
User entered 'No (N)'	System	15 Sep 2020 16:07:11

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:05:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f7be1c0d-d523-449c-b337-1408bad02dad'	System	15 Sep 2020 16:07:11
User entered 'None (1)'	System	15 Sep 2020 16:07:11

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:06:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f7be1c0d-d523-449c-b337-1408bad02dad'	System	15 Sep 2020 16:07:11
User entered '15 Sep 2020 12:06'	System	15 Sep 2020 16:07:11

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 3'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:15', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2cabfba1-3265-4c1a-bb25-af2f665e2817'	System	17 Sep 2020 13:35:28
User entered 'None (1)'	System	17 Sep 2020 13:35:28

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:17', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2cabfba1-3265-4c1a-bb25-af2f665e2817'	System	17 Sep 2020 13:35:28
User entered 'No (N)'	System	17 Sep 2020 13:35:28

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:19', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2cabfba1-3265-4c1a-bb25-af2f665e2817'	System	17 Sep 2020 13:35:28
User entered 'No (N)'	System	17 Sep 2020 13:35:28

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:20', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2cabfba1-3265-4c1a-bb25-af2f665e2817'	System	17 Sep 2020 13:35:28
User entered 'None (1)'	System	17 Sep 2020 13:35:28

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2cabfba1-3265-4c1a-bb25-af2f665e2817'	System	17 Sep 2020 13:35:28
User entered '17 Sep 2020 09:35'	System	17 Sep 2020 13:35:28

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 4'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9dfe6281-c758-4e7c-abdc-09b94d879f80'	System	18 Sep 2020 14:51:48
User entered 'None (1)'	System	18 Sep 2020 14:51:48

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9dfe6281-c758-4e7c-abdc-09b94d879f80'	System	18 Sep 2020 14:51:48
User entered 'No (N)'	System	18 Sep 2020 14:51:48

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9dfe6281-c758-4e7c-abdc-09b94d879f80'	System	18 Sep 2020 14:51:48
User entered 'No (N)'	System	18 Sep 2020 14:51:48

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9dfe6281-c758-4e7c-abdc-09b94d879f80'	System	18 Sep 2020 14:51:48
User entered 'None (1)'	System	18 Sep 2020 14:51:48

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:43', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '9dfe6281-c758-4e7c-abdc-09b94d879f80'	System	18 Sep 2020 14:51:48
User entered '18 Sep 2020 10:51'	System	18 Sep 2020 14:51:48

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 5'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:43', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b2fa243e-e703-47e2-b8dc-5ad29a0b1ca2'	System	18 Sep 2020 16:45:01
User entered 'None (1)'	System	18 Sep 2020 16:45:01

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:46', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b2fa243e-e703-47e2-b8dc-5ad29a0b1ca2'	System	18 Sep 2020 16:45:01
User entered 'No (N)'	System	18 Sep 2020 16:45:01

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b2fa243e-e703-47e2-b8dc-5ad29a0b1ca2'	System	18 Sep 2020 16:45:01
User entered 'No (N)'	System	18 Sep 2020 16:45:01

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:51', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b2fa243e-e703-47e2-b8dc-5ad29a0b1ca2'	System	18 Sep 2020 16:45:01
User entered 'None (1)'	System	18 Sep 2020 16:45:01

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:53', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b2fa243e-e703-47e2-b8dc-5ad29a0b1ca2'	System	18 Sep 2020 16:45:01
User entered '18 Sep 2020 12:44'	System	18 Sep 2020 16:45:01

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 6'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:19:18', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '023d28af-02e1-4807-93d5-3872c53fb7e9'	System	20 Sep 2020 00:21:27
User entered 'None (1)'	System	20 Sep 2020 00:21:27

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:19:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '023d28af-02e1-4807-93d5-3872c53fb7e9'	System	20 Sep 2020 00:21:27
User entered 'No (N)'	System	20 Sep 2020 00:21:27

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:19:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '023d28af-02e1-4807-93d5-3872c53fb7e9'	System	20 Sep 2020 00:21:27
User entered 'No (N)'	System	20 Sep 2020 00:21:27

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:19:25', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '023d28af-02e1-4807-93d5-3872c53fb7e9'	System	20 Sep 2020 00:21:27
User entered 'None (1)'	System	20 Sep 2020 00:21:27

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:17', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '023d28af-02e1-4807-93d5-3872c53fb7e9'	System	20 Sep 2020 00:21:27
User entered '19 Sep 2020 20:20'	System	20 Sep 2020 00:21:27

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 7'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:04', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '40e12bdc-cc13-4f59-b65f-06c3a113add9'	System	21 Sep 2020 12:20:15
User entered 'None (1)'	System	21 Sep 2020 12:20:15

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:06', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '40e12bdc-cc13-4f59-b65f-06c3a113add9'	System	21 Sep 2020 12:20:15
User entered 'No (N)'	System	21 Sep 2020 12:20:15

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '40e12bdc-cc13-4f59-b65f-06c3a113add9'	System	21 Sep 2020 12:20:15
User entered 'No (N)'	System	21 Sep 2020 12:20:15

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:08', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '40e12bdc-cc13-4f59-b65f-06c3a113add9'	System	21 Sep 2020 12:20:15
User entered 'None (1)'	System	21 Sep 2020 12:20:15

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '40e12bdc-cc13-4f59-b65f-06c3a113add9'	System	21 Sep 2020 12:20:15
User entered '21 Sep 2020 08:20'	System	21 Sep 2020 12:20:15

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'None (0)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:14', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'None (0)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:18', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d' User entered 'None (0)'	System	14 Sep 2020 22:02:18
	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'None (0)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:24', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'None (0)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'None (0)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered 'No (N)'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T18:01:31', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '13b529c0-90bb-48e5-94c0-63aec2d9714d'	System	14 Sep 2020 22:02:18
User entered '14 Sep 2020 18:01'	System	14 Sep 2020 22:02:18

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 17:53'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 20:23'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:47', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:19:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:20:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:20:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'None (0)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:20:06', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered 'No (N)'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-14T21:20:08', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'c3e8c146-b126-4612-969b-acf3d26dbaa0'	System	15 Sep 2020 01:20:17
User entered '14 Sep 2020 21:20'	System	15 Sep 2020 01:20:17

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '14 Sep 2020 21:18'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 2'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:25', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:27', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:28', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'None (0)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:33', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered 'No (N)'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-15T12:03:38', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '7cfd18aa-81d6-4db6-8e4b-5e0efca27aff'	System	15 Sep 2020 16:04:59
User entered '15 Sep 2020 12:03'	System	15 Sep 2020 16:04:59

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 3'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:57', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:34:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:02', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'None (0)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered 'No (N)'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-17T09:35:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'a35e3e62-4b7b-41e9-8bff-6b9205994324'	System	17 Sep 2020 13:35:16
User entered '17 Sep 2020 09:35'	System	17 Sep 2020 13:35:16

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 4'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:46', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:52', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:56', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'None (0)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:50:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered 'No (N)'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T10:51:06', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fc57471b-f48b-43b9-ba27-a5f0fc06c4d8'	System	18 Sep 2020 14:51:13
User entered '18 Sep 2020 10:51'	System	18 Sep 2020 14:51:13

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 5'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:57', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:44:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:07', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:09', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'None (0)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:11', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered 'No (N)'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-18T12:45:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b7014fc7-f510-4ba8-870a-26a61ca77697'	System	18 Sep 2020 16:45:21
User entered '18 Sep 2020 12:45'	System	18 Sep 2020 16:45:21

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 6'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:22', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:20:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'None (0)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered 'No (N)'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-19T20:21:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0721d899-59ae-4a9a-bc9b-d639fcf453a5'	System	20 Sep 2020 00:21:47
User entered '19 Sep 2020 20:21'	System	20 Sep 2020 00:21:47

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	14 Sep 2020 21:37:34
User entered 'Day 7'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:49', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:51', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:52', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:55', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:57', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'None (0)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:19:58', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered 'No (N)'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-09-21T08:20:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fb588615-33af-4092-8fb5-e71915bbfc24'	System	21 Sep 2020 12:20:05
User entered '21 Sep 2020 08:20'	System	21 Sep 2020 12:20:05

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:37:34

US3722247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:27:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:37:34

US3722247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 19:49:10

US3722247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '21 Sep 2020'	Kayla Peay (b) (4)	23 Sep 2020 19:49:10

US3722247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	23 Sep 2020 19:49:10

US3722247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Kayla Peay (b) (4)	23 Sep 2020 19:49:10

US3722247

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 19:49:13

US3722247

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	23 Sep 2020 19:49:13

US3722247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Sep 2020 15:26:11

US3722247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '28 Sep 2020'	Kayla Peay (b) (4)	28 Sep 2020 15:26:11

US3722247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	28 Sep 2020 15:26:11

US3722247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Kayla Peay (b) (4)	28 Sep 2020 15:26:11

US3722247

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Sep 2020 15:26:14

US3722247

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	28 Sep 2020 15:26:14

US3722247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Oct 2020 20:03:42

US3722247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered '5 Oct 2020'	Kayla Peay (b) (4)	07 Oct 2020 20:03:42

US3722247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	07 Oct 2020 20:03:42

US3722247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered empty.	Kayla Peay (b) (4)	07 Oct 2020 20:03:42

US3722247

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
User entered 'Yes (Y)'	Kayla Peay (b) (4)	07 Oct 2020 20:03:45

US3722247

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '1'	System	07 Oct 2020 20:03:45

US3722247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:07

US3722247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '16 Oct 2020'	Marlee Smith (b) (4)	19 Oct 2020 12:33:07

US3722247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:07

US3722247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'VISIT3'	System	19 Oct 2020 12:33:07

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '16 Oct 2020'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:21'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '16 Oct 2020 17:21'	System	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '97.8' F	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered empty.	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '79'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'bpm'	System	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'breaths/min'	System	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '120'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '86'	Marlee Smith (b) (4)	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'mmHg'	System	19 Oct 2020 12:33:33

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40

US3722247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40

US3722247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:38

US3722247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '16 Oct 2020'	Marlee Smith (b) (4)	19 Oct 2020 12:33:38

US3722247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:46

US3722247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '16 Oct 2020'	Marlee Smith (b) (4)	19 Oct 2020 12:33:46

US3722247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered '17:21'	Marlee Smith (b) (4)	19 Oct 2020 12:33:46

US3722247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '16 Oct 2020 17:21'	System	19 Oct 2020 12:33:46

US3722247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	19 Oct 2020 12:33:48

US3722247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered '1'	System	19 Oct 2020 12:33:48

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 64'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 71'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

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)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-10-20T15:09:22', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '06096af8-3f6a-4aff-a1f0-5d9d2cdcf549'	System	20 Oct 2020 19:09:38
User entered 'No (N)'	System	20 Oct 2020 19:09:38

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-10-20T15:09:29', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '06096af8-3f6a-4aff-a1f0-5d9d2cdcf549'	System	20 Oct 2020 19:09:38
User entered 'No (N)'	System	20 Oct 2020 19:09:38

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-10-20T15:09:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '06096af8-3f6a-4aff-a1f0-5d9d2cdcf549' User entered '20 Oct 2020 15:09:32'	System	20 Oct 2020 19:09:38
	System	20 Oct 2020 19:09:38

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:15:30
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 78'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 92'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered 'Day 99'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Please 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 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 22:37:36

US3722247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:54:52
Data entry locked.	System	13 Aug 2020 22:37:36
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 22:37:36

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-11-23T17:16:02', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'dd565ebe-cc88-411d-b5b1-47c3a163ac07'	System	23 Nov 2020 22:16:19
User entered 'No (N)'	System	23 Nov 2020 22:16:19

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-11-23T17:16:08', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'dd565ebe-cc88-411d-b5b1-47c3a163ac07'	System	23 Nov 2020 22:16:19
User entered 'No (N)'	System	23 Nov 2020 22:16:19

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-11-23T17:16:11', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'dd565ebe-cc88-411d-b5b1-47c3a163ac07'	System	23 Nov 2020 22:16:19
User entered '23 Nov 2020 17:16:11'	System	23 Nov 2020 22:16:19

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-11-30T10:48:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2c36a32c-f0fa-4770-8ff9-70e83ae2c69b'	System	30 Nov 2020 15:48:28
User entered 'No (N)'	System	30 Nov 2020 15:48:28

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-11-30T10:48:16', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2c36a32c-f0fa-4770-8ff9-70e83ae2c69b'	System	30 Nov 2020 15:48:28
User entered 'No (N)'	System	30 Nov 2020 15:48:28

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-11-30T10:48:18', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '2c36a32c-f0fa-4770-8ff9-70e83ae2c69b'	System	30 Nov 2020 15:48:28
User entered '30 Nov 2020 10:48:18'	System	30 Nov 2020 15:48:28

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-12-09T10:23:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ce3f9ad0-9770-43c5-9657-a285090565d4'	System	09 Dec 2020 15:23:39
User entered 'No (N)'	System	09 Dec 2020 15:23:39

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-12-09T10:23:33', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ce3f9ad0-9770-43c5-9657-a285090565d4'	System	09 Dec 2020 15:23:39
User entered 'No (N)'	System	09 Dec 2020 15:23:39

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-12-09T10:23:36', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ce3f9ad0-9770-43c5-9657-a285090565d4'	System	09 Dec 2020 15:23:39
User entered '09 Dec 2020 10:23:36'	System	09 Dec 2020 15:23:39

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-12-12T12:02:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b974456-f8c8-4ed3-9571-4c290b0565ce'	System	12 Dec 2020 17:02:32
User entered 'No (N)'	System	12 Dec 2020 17:02:32

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-12-12T12:02:24', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b974456-f8c8-4ed3-9571-4c290b0565ce'	System	12 Dec 2020 17:02:32
User entered 'No (N)'	System	12 Dec 2020 17:02:32

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-12-12T12:02:27', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5b974456-f8c8-4ed3-9571-4c290b0565ce' User entered '12 Dec 2020 12:02:27'	System	12 Dec 2020 17:02:32
	System	12 Dec 2020 17:02:32

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-12-22T12:25:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'e296bc9c-58f6-4ed1-8ab8-e35975e733ef'	System	22 Dec 2020 16:25:37
User entered 'No (N)'	System	22 Dec 2020 16:25:37

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-12-22T12:25:30', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'e296bc9c-58f6-4ed1-8ab8-e35975e733ef'	System	22 Dec 2020 16:25:37
User entered 'No (N)'	System	22 Dec 2020 16:25:37

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-12-22T12:25:32', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'e296bc9c-58f6-4ed1-8ab8-e35975e733ef' User entered '22 Dec 2020 12:25:32'	System	22 Dec 2020 16:25:37
	System	22 Dec 2020 16:25:37

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2020-12-26T08:04:54', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'd235d7a9-c497-484d-a14c-5ca249d76b86'	System	26 Dec 2020 12:05:06
User entered 'No (N)'	System	26 Dec 2020 12:05:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2020-12-26T08:04:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'd235d7a9-c497-484d-a14c-5ca249d76b86'	System	26 Dec 2020 12:05:06
User entered 'No (N)'	System	26 Dec 2020 12:05:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2020-12-26T08:05:01', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'd235d7a9-c497-484d-a14c-5ca249d76b86'	System	26 Dec 2020 12:05:06
User entered '26 Dec 2020 08:05:01'	System	26 Dec 2020 12:05:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-01-04T12:05:59', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '72644e84-48db-48e7-a7ba-587e48681b06'	System	04 Jan 2021 17:06:09
User entered 'No (N)'	System	04 Jan 2021 17:06:09

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-01-04T12:06:03', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '72644e84-48db-48e7-a7ba-587e48681b06'	System	04 Jan 2021 17:06:09
User entered 'No (N)'	System	04 Jan 2021 17:06:09

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-01-04T12:06:05', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '72644e84-48db-48e7-a7ba-587e48681b06'	System	04 Jan 2021 17:06:09
User entered '04 Jan 2021 12:06:05'	System	04 Jan 2021 17:06:09

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-01-09T16:31:35', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'eb2041d0-a328-4d8a-894c-d166490d42d4'	System	09 Jan 2021 21:31:49
User entered 'No (N)'	System	09 Jan 2021 21:31:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-01-09T16:31:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'eb2041d0-a328-4d8a-894c-d166490d42d4'	System	09 Jan 2021 21:31:49
User entered 'No (N)'	System	09 Jan 2021 21:31:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-01-09T16:31:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'eb2041d0-a328-4d8a-894c-d166490d42d4'	System	09 Jan 2021 21:31:49
User entered '09 Jan 2021 16:31:42'	System	09 Jan 2021 21:31:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-01-16T10:48:34', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f18621d5-5c19-4c66-9ee6-b18704d0e555'	System	16 Jan 2021 15:48:43
User entered 'No (N)'	System	16 Jan 2021 15:48:43

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-01-16T10:48:37', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f18621d5-5c19-4c66-9ee6-b18704d0e555'	System	16 Jan 2021 15:48:43
User entered 'No (N)'	System	16 Jan 2021 15:48:43

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-01-16T10:48:39', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'f18621d5-5c19-4c66-9ee6-b18704d0e555'	System	16 Jan 2021 15:48:43
User entered '16 Jan 2021 10:48:39'	System	16 Jan 2021 15:48:43

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-01-26T12:28:47', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3533b32d-e32c-452f-b5db-52d6b8af4a65'	System	26 Jan 2021 17:56:57
User entered 'No (N)'	System	26 Jan 2021 17:56:57

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-01-26T12:28:48', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3533b32d-e32c-452f-b5db-52d6b8af4a65'	System	26 Jan 2021 17:56:57
User entered 'No (N)'	System	26 Jan 2021 17:56:57

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-01-26T12:28:50', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3533b32d-e32c-452f-b5db-52d6b8af4a65'	System	26 Jan 2021 17:56:57
User entered '26 Jan 2021 12:28:50'	System	26 Jan 2021 17:56:57

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-01-31T15:23:09', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '44c5735e-3bfd-4088-a78f-f7dd2222146d'	System	31 Jan 2021 20:23:20
User entered 'No (N)'	System	31 Jan 2021 20:23:20

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-01-31T15:23:13', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '44c5735e-3bfd-4088-a78f-f7dd2222146d'	System	31 Jan 2021 20:23:20
User entered 'No (N)'	System	31 Jan 2021 20:23:20

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-01-31T15:23:15', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '44c5735e-3bfd-4088-a78f-f7dd2222146d'	System	31 Jan 2021 20:23:20
User entered '31 Jan 2021 15:23:15'	System	31 Jan 2021 20:23:20

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-02-07T17:38:10', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3bc5703b-388b-4029-9d62-4df36889224a'	System	07 Feb 2021 22:38:18
User entered 'No (N)'	System	07 Feb 2021 22:38:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-02-07T17:38:12', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3bc5703b-388b-4029-9d62-4df36889224a'	System	07 Feb 2021 22:38:18
User entered 'No (N)'	System	07 Feb 2021 22:38:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-07T17:38:15', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3bc5703b-388b-4029-9d62-4df36889224a'	System	07 Feb 2021 22:38:18
User entered '07 Feb 2021 17:38:15'	System	07 Feb 2021 22:38:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-02-15T22:34:40', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6d67f275-b4b9-47c1-b267-97d0d48dfd4f'	System	16 Feb 2021 03:34:49
User entered 'No (N)'	System	16 Feb 2021 03:34:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-02-15T22:34:42', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6d67f275-b4b9-47c1-b267-97d0d48dfd4f'	System	16 Feb 2021 03:34:49
User entered 'No (N)'	System	16 Feb 2021 03:34:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-15T22:34:44', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '6d67f275-b4b9-47c1-b267-97d0d48dfd4f'	System	16 Feb 2021 03:34:49
User entered '15 Feb 2021 22:34:44'	System	16 Feb 2021 03:34:49

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-02-20T10:14:21', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '92f5a8eb-83ef-4a8a-b707-9f378c3cfd83'	System	20 Feb 2021 15:14:35
User entered 'No (N)'	System	20 Feb 2021 15:14:35

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-02-20T10:14:23', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '92f5a8eb-83ef-4a8a-b707-9f378c3cfd83'	System	20 Feb 2021 15:14:35
User entered 'No (N)'	System	20 Feb 2021 15:14:35

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-20T10:14:26', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '92f5a8eb-83ef-4a8a-b707-9f378c3cfd83'	System	20 Feb 2021 15:14:35
User entered '20 Feb 2021 10:14:26'	System	20 Feb 2021 15:14:35

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-02-28T08:54:47-07:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '256077bf-f910-4c97-aca3-753229839468'	System	28 Feb 2021 15:54:54
User entered 'No (N)'	System	28 Feb 2021 15:54:54

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-02-28T08:54:48-07:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '256077bf-f910-4c97-aca3-753229839468'	System	28 Feb 2021 15:54:54
User entered 'No (N)'	System	28 Feb 2021 15:54:54

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-28T08:54:51-07:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '256077bf-f910-4c97-aca3-753229839468' User entered '28 Feb 2021 08:54:51'	System	28 Feb 2021 15:54:54
	System	28 Feb 2021 15:54:54

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-03-08T17:51:46-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3da7ea3b-dd05-4371-a8e9-aa52a7ac7c7a'	System	08 Mar 2021 22:52:02
User entered 'No (N)'	System	08 Mar 2021 22:52:02

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-03-08T17:51:52-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3da7ea3b-dd05-4371-a8e9-aa52a7ac7c7a'	System	08 Mar 2021 22:52:02
User entered 'No (N)'	System	08 Mar 2021 22:52:02

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-03-08T17:51:55-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '3da7ea3b-dd05-4371-a8e9-aa52a7ac7c7a'	System	08 Mar 2021 22:52:02
User entered '08 Mar 2021 17:51:55'	System	08 Mar 2021 22:52:02

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-03-13T08:50:06-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5fc95395-dfcb-4a36-9bd9-3511e7779d4b'	System	13 Mar 2021 13:50:18
User entered 'No (N)'	System	13 Mar 2021 13:50:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-03-13T08:50:08-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5fc95395-dfcb-4a36-9bd9-3511e7779d4b'	System	13 Mar 2021 13:50:18
User entered 'No (N)'	System	13 Mar 2021 13:50:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-03-13T08:50:10-05:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5fc95395-dfcb-4a36-9bd9-3511e7779d4b'	System	13 Mar 2021 13:50:18
User entered '13 Mar 2021 08:50:10'	System	13 Mar 2021 13:50:18

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-03-20T08:20:07-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5337fb32-29aa-4da0-8740-1349004da44d'	System	20 Mar 2021 12:20:16
User entered 'No (N)'	System	20 Mar 2021 12:20:16

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-03-20T08:20:10-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5337fb32-29aa-4da0-8740-1349004da44d'	System	20 Mar 2021 12:20:16
User entered 'No (N)'	System	20 Mar 2021 12:20:16

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-03-20T08:20:12-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '5337fb32-29aa-4da0-8740-1349004da44d' User entered '20 Mar 2021 08:20:12'	System	20 Mar 2021 12:20:16
	System	20 Mar 2021 12:20:16

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-03-29T11:53:34-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0c297f9d-3fda-4938-8d0b-9849e1c4baea'	System	29 Mar 2021 15:53:52
User entered 'No (N)'	System	29 Mar 2021 15:53:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-03-29T11:53:44-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0c297f9d-3fda-4938-8d0b-9849e1c4baea'	System	29 Mar 2021 15:53:52
User entered 'No (N)'	System	29 Mar 2021 15:53:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-03-29T11:53:46-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '0c297f9d-3fda-4938-8d0b-9849e1c4baea' User entered '29 Mar 2021 11:53:46'	System	29 Mar 2021 15:53:52
	System	29 Mar 2021 15:53:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-04-03T10:17:15-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '75540d70-57a7-4b0e-9324-2209f6ba84f2' User entered 'No (N)'	System	03 Apr 2021 14:17:29
	System	03 Apr 2021 14:17:29

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-04-03T10:17:18-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '75540d70-57a7-4b0e-9324-2209f6ba84f2'	System	03 Apr 2021 14:17:29
User entered 'No (N)'	System	03 Apr 2021 14:17:29

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-04-03T10:17:21-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '75540d70-57a7-4b0e-9324-2209f6ba84f2' User entered '03 Apr 2021 10:17:21'	System	03 Apr 2021 14:17:29
	System	03 Apr 2021 14:17:29

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-04-10T15:36:53-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fbb9028b-adc7-435f-802c-c57bcd575788'	System	10 Apr 2021 19:37:06
User entered 'No (N)'	System	10 Apr 2021 19:37:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-04-10T15:36:59-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fbb9028b-adc7-435f-802c-c57bcd575788'	System	10 Apr 2021 19:37:06
User entered 'No (N)'	System	10 Apr 2021 19:37:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-04-10T15:37:01-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'fbb9028b-adc7-435f-802c-c57bcd575788' User entered '10 Apr 2021 15:37:01'	System	10 Apr 2021 19:37:06
	System	10 Apr 2021 19:37:06

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-04-20T16:52:26-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac31129d-b4bf-4f8e-a3c1-56a2be249387'	System	20 Apr 2021 20:52:36
User entered 'No (N)'	System	20 Apr 2021 20:52:36

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-04-20T16:52:28-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac31129d-b4bf-4f8e-a3c1-56a2be249387'	System	20 Apr 2021 20:52:36
User entered 'No (N)'	System	20 Apr 2021 20:52:36

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-04-20T16:52:30-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'ac31129d-b4bf-4f8e-a3c1-56a2be249387'	System	20 Apr 2021 20:52:36
User entered '20 Apr 2021 16:52:30'	System	20 Apr 2021 20:52:36

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[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 (4bdf1659668cb742)', Time: '2021-05-02T12:56:51-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b4f99eb7-676e-47cd-979b-008aab715d29'	System	02 May 2021 16:57:00
User entered 'No (N)'	System	02 May 2021 16:57:00

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Have you been exposed to someone with 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 (4bdf1659668cb742)', Time: '2021-05-02T12:56:53-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b4f99eb7-676e-47cd-979b-008aab715d29'	System	02 May 2021 16:57:00
User entered 'No (N)'	System	02 May 2021 16:57:00

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-05-02T12:56:55-04:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: 'b4f99eb7-676e-47cd-979b-008aab715d29'	System	02 May 2021 16:57:00
User entered '02 May 2021 12:56:55'	System	02 May 2021 16:57:00

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:54:52

US3722247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:27:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:54:52
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:54:52

US3722247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:27:23

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 03:34:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-28T08:54:38-07:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '10e1a4bf-d8a9-44b4-942d-85e8b2f2a310'	System	28 Feb 2021 15:54:44
User entered 'No (N)'	System	28 Feb 2021 15:54:44

US3722247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:27:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bdf1659668cb742)', Time: '2021-02-28T08:54:40-07:00', User OID: 'PatientReportedOutcome (US3722247)', ODM File OID: '10e1a4bf-d8a9-44b4-942d-85e8b2f2a310'	System	28 Feb 2021 15:54:44
User entered '28 Feb 2021 08:54:40'	System	28 Feb 2021 15:54:44

US3722247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:29:30
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	09 Nov 2020 15:48:58

US3722247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:29:30
User entered '6 Nov 2020'	Marlee Smith (b) (4)	09 Nov 2020 15:48:58

US3722247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:29:30
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	09 Nov 2020 15:48:58

US3722247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:29:30
User entered empty.	Marlee Smith (b) (4)	09 Nov 2020 15:48:58

US3722247

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:27:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:29:52
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Nov 2020 15:48:21

US3722247

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:47:40
User entered 'I'	System	09 Nov 2020 15:48:21

US3722247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Dec 2020 20:04:56

US3722247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '10 Dec 2020'	Amy Ford (b) (4)	10 Dec 2020 20:04:56

US3722247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	10 Dec 2020 20:04:56

US3722247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	Amy Ford (b) (4)	10 Dec 2020 20:04:56

US3722247

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Dec 2020 20:05:02

US3722247

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:32
User entered '1'	System	10 Dec 2020 20:05:02

US3722247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	15 Jan 2021 14:29:44

US3722247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '15 Jan 2021'	Taylor Wilson (b) (4)	15 Jan 2021 14:29:44

US3722247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	Taylor Wilson (b) (4)	15 Jan 2021 14:31:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Taylor Wilson (b) (4)	15 Jan 2021 14:29:44
	(b) (4)	

US3722247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	15 Jan 2021 14:31:32
Please review and reconcile.' (Site from System).		
User entered 'Several attempts have been made to contact subject for site call visit but have not been successful with reaching patient or received a call back.' reason for change: Data Entry Error	Taylor Wilson (b) (4)	15 Jan 2021 14:31:32
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	15 Jan 2021 14:31:24
Please review and reconcile.' (Site from System).		
User entered empty.	Taylor Wilson (b) (4)	15 Jan 2021 14:29:44
	(b) (4)	

US3722247

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	15 Jan 2021 14:29:51

US3722247

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:50
User entered 'I'	System	15 Jan 2021 14:29:51

US3722247

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	08 Feb 2021 19:21:08

US3722247

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '08 Feb 2021'	Taylor Wilson (b) (4)	08 Feb 2021 19:21:08

US3722247

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	08 Feb 2021 19:21:08

US3722247

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	Taylor Wilson (b) (4)	08 Feb 2021 19:21:08

US3722247

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	08 Feb 2021 19:21:14

US3722247

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:00:30
User entered 'I'	System	08 Feb 2021 19:21:14

US3722247

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:27:31

US3722247

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:27:31

US3722247

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[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 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	05 Mar 2021 13:27:31

US3722247

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'VISIT4'	System	05 Mar 2021 13:27:31

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '4 Mar 2021'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '16:06'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '4 Mar 2021 16:06'	System	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '98' F	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'Oral (Oral)'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered empty.	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '80'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'bpm'	System	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '17'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'breaths/min'	System	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '139'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'mmHg'	System	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '85'	Marlee Smith (b) (4) (b) (4)	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered 'mmHg'	System	30 Mar 2021 17:01:58

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53

US3722247

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53

US3722247

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User closed query 'Per CDM: Visit 4 Day 209 (1) and OL-29 (1) are both dated 04Mar2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:12:11
Query 'Per CDM: Visit 4 Day 209 (1) and OL-29 (1) are both dated 04Mar2021. However, the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	26 Mar 2021 13:01:36
Signature has been broken.	(b) (4)	
	Marlee Smith (b) (4)	26 Mar 2021 13:01:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	26 Mar 2021 13:01:21
User opened query 'Per CDM: Visit 4 Day 209 (1) and OL-29 (1) are both dated 04Mar2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:14:58
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'No (N)'	(b) (4)	
	Marlee Smith (b) (4)	05 Mar 2021 13:27:40
	(b) (4)	

US3722247

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
Signature has been broken.	Marlee Smith (b) (4)	26 Mar 2021 13:01:21
	(b) (4)	
User entered '4 Mar 2021' reason for change: Data Entry Error	Marlee Smith (b) (4)	26 Mar 2021 13:01:21
	(b) (4)	
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	05 Mar 2021 13:27:40
	(b) (4)	

US3722247

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:27:50

US3722247

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:27:50

US3722247

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered '16:25'	Marlee Smith (b) (4)	05 Mar 2021 13:27:50

US3722247

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '4 Mar 2021 16:25'	System	05 Mar 2021 13:27:50

US3722247

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:27:36
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:27:53

US3722247

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:53
User entered '1'	System	05 Mar 2021 13:27:53

US3722247

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	09 Apr 2021 17:51:51
	(b) (4)	

US3722247

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
User entered '09 Apr 2021'	Taylor Wilson (b) (4)	09 Apr 2021 17:51:51
	(b) (4)	

US3722247

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	09 Apr 2021 17:51:51
	(b) (4)	

US3722247

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	09 Apr 2021 17:51:51
	(b) (4)	

US3722247

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	09 Apr 2021 17:52:00
	(b) (4)	

US3722247

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 17:52:00

US3722247

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

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Feb 2021 13:08:19

US3722247

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

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:19

US3722247

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

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Clinic (Clinic)'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:19

US3722247

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

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 13:08:19

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '0'	Marlee Smith (b) (4)	22 Apr 2021 13:05:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:34:40

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:41:28
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 13:05:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 13:05:20
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 10:33:52
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:34:40

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1'	System	02 Feb 2021 13:08:27

US3722247

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

Form: Unblinding

Generated On: 12 Aug 2021 13:27:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'I'	System	02 Feb 2021 13:08:27

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered empty.	System	02 Feb 2021 13:11:08
DataPoint set to visible.	System	02 Feb 2021 13:08:27

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered empty.	System	02 Feb 2021 13:11:08
DataPoint set to visible.	System	02 Feb 2021 13:08:27

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '16:55'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1 Feb 2021 16:55'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '98' F	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '85'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'bpm'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '16'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'breaths/min'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '134'	Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'mmHg'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '85'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'mmHg'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:27:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered empty.	System	02 Feb 2021 13:11:08
DataPoint set to visible.	System	02 Feb 2021 13:08:27

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '17:36'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1 Feb 2021 17:36'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '98.4' F	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '77'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'bpm'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '17'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'breaths/min'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '114'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'mmHg'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '82'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:11:08

US3722247

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'mmHg'	System	02 Feb 2021 13:11:08

US3722247

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:05

US3722247

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:05

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Urine (URINE)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Negative (NEGATIVE)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:12

US3722247

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered empty.	System	02 Feb 2021 13:09:12

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	Marlee Smith (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'mRNA-1273'	System	02 Feb 2021 13:09:38
DataPoint set to visible.	System	02 Feb 2021 13:08:27

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '17:04'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1 Feb 2021 17:04'	System	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'ONCE'	System	02 Feb 2021 13:09:38

US3722247

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

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 13:09:38

US3722247

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:36

US3722247

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:36

US3722247

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '16:50'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:36

US3722247

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1 Feb 2021 16:50'	System	02 Feb 2021 13:08:36

US3722247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:44

US3722247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '1 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	02 Feb 2021 13:08:44

US3722247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '16:52'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:44

US3722247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered '1 Feb 2021 16:52'	System	02 Feb 2021 13:08:44

US3722247

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

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	02 Feb 2021 13:08:50

US3722247

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

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:06
User entered 'I'	System	02 Feb 2021 13:08:50

US3722247

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 20:15:58

US3722247

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '8 Feb 2021'	Marlee Smith (b) (4)	02 Mar 2021 20:15:58

US3722247

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	02 Mar 2021 20:15:58

US3722247

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	Marlee Smith (b) (4)	02 Mar 2021 20:15:58

US3722247

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 20:16:01

US3722247

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User entered 'I'	System	02 Mar 2021 20:16:01

US3722247

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:19:28
User entered 'I'	System	02 Mar 2021 20:16:01
DataPoint set to visible.	System	02 Mar 2021 20:16:01

US3722247

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:28:05

US3722247

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:28:05

US3722247

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	05 Mar 2021 13:28:05

US3722247

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'OLD29'	System	05 Mar 2021 13:28:05

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '16:06'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered '4 Mar 2021 16:06'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '98' F	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '80'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'bpm'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '17'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'breaths/min'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '139'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'mmHg'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '85'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'mmHg'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '17:14'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered '4 Mar 2021 17:14'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '99.1' F	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '93'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'bpm'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '18'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'breaths/min'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '128'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'mmHg'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '83'	Marlee Smith (b) (4)	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'mmHg'	System	05 Mar 2021 13:28:57

US3722247

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:29:18

US3722247

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:29:18

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Urine (URINE)'	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 09:16:17
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy test was positive' (Site from System).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 20:06:23
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	05 Mar 2021 13:29:41
User entered 'Positive (POSITIVE)'	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'No (N)'	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	Marlee Smith (b) (4)	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered empty.	System	05 Mar 2021 13:29:41

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User closed query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject has positive results. Please review and update or explain otherwise.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 09:16:25
Query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' answered with 'ePIP was sent and investigator talked with subject who said she was ok with getting the second dose' (Site from System).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:32:17
User opened query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' (Site from System).	System	05 Mar 2021 13:30:12
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	(b) (4) Marlee Smith (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered empty.	Marlee Smith (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'mRNA-1273'	System	05 Mar 2021 13:30:12
DataPoint set to visible.	System	02 Mar 2021 20:16:01

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '4 Mar 2021'	Marlee Smith (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered '16:44'	Marlee Smith (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered '4 Mar 2021 16:44'	System	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'ONCE'	System	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:27:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 13:30:12

US3722247

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Mar 2021 13:32:22

US3722247

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:07:14
User entered 'I'	System	05 Mar 2021 13:32:22

US3722247

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	11 Mar 2021 14:28:48

US3722247

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered '11 Mar 2021'	Taylor Wilson (b) (4)	11 Mar 2021 14:28:48

US3722247

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	11 Mar 2021 14:28:48

US3722247

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:27:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered empty.	Taylor Wilson (b) (4)	11 Mar 2021 14:28:48

US3722247

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:11
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	11 Mar 2021 14:28:52

US3722247

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:27:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:59
User entered 'I'	System	11 Mar 2021 14:28:52

US3722247

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	12 Apr 2021 19:00:47
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '12 Apr 2021'	Marlee Smith (b) (4)	12 Apr 2021 19:00:47
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	12 Apr 2021 19:00:47
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:27:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	12 Apr 2021 19:00:47

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '12 Apr 2021'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '11:50'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:50'	System	12 Apr 2021 19:01:14

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '98' F	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '74'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 19:01:14

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '15'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 19:01:14

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '121'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:01:14

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '81'	Marlee Smith (b) (4)	12 Apr 2021 19:01:14
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:27:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:01:14

US3722247

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	12 Apr 2021 19:01:17
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:27:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	12 Apr 2021 19:01:17
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	12 Apr 2021 19:01:25
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '12 Apr 2021'	Marlee Smith (b) (4)	12 Apr 2021 19:01:25
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '11:55'	Marlee Smith (b) (4)	12 Apr 2021 19:01:25
	(b) (4)	

US3722247

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:27:23

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

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:55'	System	12 Apr 2021 19:01:25

US3722247

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:27:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Sara Poff (b) (4)	16 Feb 2021 22:20:10
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:27:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:52
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:26:46

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 12:29:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:29:18
Data point term sent to Coder	System	14 Aug 2020 12:27:57
User entered 'levothyroxine'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:27:31

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'hypothyroidism'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '100'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'ug (ug)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'once daily (QD)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Oral (ORAL)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 20:44:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:27:31
User entered 'un Dec 2018'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:27:31

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:27:31
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:27:31

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:27:31

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:27:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:27:31

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:47
Data point term sent to Coder Coding entries removed.	System Amy Ford (b) (4) (b) (4)	16 Oct 2020 13:25:20 16 Oct 2020 13:25:02
User entered 'TRETINOIN 0.25%' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	16 Oct 2020 13:25:02
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:30:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 12:30:19
Data point term sent to Coder User entered 'tretinoin'	System Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:28:57 14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'acne'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:21:33
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'updated' (Site from DM).	Amy Ford (b) (4) (b) (4)	16 Oct 2020 13:25:10
User entered '1' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	16 Oct 2020 13:25:02
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:53:16
User entered '0.25'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Other (OTHER)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Application' reason for change: Data Entry Error	Amy Ford (b) (4)	16 Oct 2020 13:25:02
	(b) (4)	
User entered 'per cent'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'once daily (QD)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Topical (TOPICAL)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 20:44:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 12:28:16
User entered 'un Dec 2018'	Kayla Peay (b) (4) (b) (4)	14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:16
	(b) (4)	

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:27:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 12:28:16

US3722247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:27:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:54:08
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	14 Aug 2020 12:28:40
	(b) (4)	