

US3832250 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:31:43

All time stamps listed in this document are displayed in GMT

US3832250

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

[Participant ID](#)

US3832250

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

US3832250

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:33:39

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Date of Birth (MMM yyyy)	(b) (6) 1992
Age	28
Age Units	YEARS
Age (Derived)	28
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:33:39

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Date of Informed Consent (<i>dd MMM yyyy</i>)	24 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:33:39

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 14:33:39

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Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:42 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 15:42
Height (<i>xxx.x</i>)	162.6 cm
Weight (<i>xxx.x</i>)	85.3 kg
BMI (<i>xxx.x</i>)	32.26324 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:33:39

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Date of assessment (*dd MMM yyyy*) 24 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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	24 AUG 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:33:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:33:40

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What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 106306

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:33:40

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	15:42 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 15:42
Temperature (xxx.x)	98.0 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 17:06
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:33:40

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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) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 16:35 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 16:35

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

15:55 (24 HR)

Collection date and time (derived)

24 AUG 2020 15:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	24 AUG 2020 15:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

24 AUG 2020 17:07

PC Open Date & Time

24 AUG 2020 16:55

PC Close Date & Time

24 AUG 2020 19:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 20:24

PC Open Date & Time

24 AUG 2020 20:20

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

25 AUG 2020 12:03

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 12:07

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

27 AUG 2020 12:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

28 AUG 2020 14:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

24 AUG 2020 17:08

PC Open Date & Time

24 AUG 2020 16:55

PC Close Date & Time

24 AUG 2020 19:25

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:25

PC Open Date & Time

24 AUG 2020 20:20

PC Close Date & Time

25 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:05

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 14:18

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 13:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:15

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:08
PC Open Date & Time	24 AUG 2020 16:55
PC Close Date & Time	24 AUG 2020 19:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:26
PC Open Date & Time	24 AUG 2020 20:20
PC Close Date & Time	25 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:03
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:06
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 14:18
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:20
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:15
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:09

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:09

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

PC Time stamp 31 AUG 2020 12:09

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 12:09
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3832250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:06
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	21 SEP 2020
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 checked="" type="radio"/>
	No <input type="radio"/>
Collection date	21 SEP 2020
Collection time	13:15
Collection date and time (derived)	21 SEP 2020 13:15

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☒
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3832250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

13:46 (24 HR)

Collection date and time (derived)

21 SEP 2020 13:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:44	21 SEP 2020 13:44
Nasopharyngeal Swab 2	No		

US3832250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:39

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 08:38
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3832250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

08:52 (24 HR)

Collection date and time (derived)

20 OCT 2020 08:52

US3832250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:33:40

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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 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	26 OCT 2020 11:58:08
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

01 NOV 2020 11:40:21

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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 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	09 NOV 2020 09:43:55
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 19:29:24

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 00:02:05

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 09:00:10

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 00:02:19

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 09:51:02

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 11:22:03

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 09:57:06

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 159

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 09:25:28

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 04:16:53

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 10:34:33

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 13:25:04

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 MAR 2021 09:37:57
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:02:29

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 18:29:27

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 08:50:10

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 08:34:21

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 08:21:20

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 18:20:12

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 08:35:02

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 285

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 292

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 327

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 362

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 369

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 390

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2021 00:01
Patient Cloud Close Date & Time	26 SEP 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 425

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 439

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 453

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 474

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 495

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 544

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 551

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 656

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 677

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 705

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 712

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 719

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 761

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 775

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 782

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

DAY 789

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3832250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:31:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 13:30:36

US3832250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:40:03

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

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

Visit date (dd MMM yyyy)	30 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
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US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3832250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

08:49 (24 HR)

Collection date and time (derived)

30 MAR 2021 08:49

US3832250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832250

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:21:39

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832250

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

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

US3832250

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832250

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:43

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3832250

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:31:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832250

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

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

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3832250

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:18:28

Generated On: 12 Aug 2021 13:31:43

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☐ Placebo ☐ Not Administered ☒

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3832250

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

10:02 (24 HR)

Collection date and time (derived)

21 JAN 2021 10:02

US3832250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	10:00
---------------------------------	-------

Collection Date and Time (derived)	21 JAN 2021 10:00
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US3832250

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:14:21

Generated On: 12 Aug 2021 13:31:43

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:14:21

Generated On: 12 Aug 2021 13:31:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	STARTED PHENEGAN
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:14:21

Generated On: 12 Aug 2021 13:31:43

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:14:21

Generated On: 12 Aug 2021 13:31:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

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

Yes ☒

No ☐

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

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Name of Medication NUVARING

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify DEVICE

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

If frequency is Other, specify

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

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EAB) (1725)

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 SEP 2020	
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 checked="" type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Name of Medication PHENEGRAN

Prophylaxis Yes ☐
No ☒

Indication AE- NAUSEA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3832250

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 21:39:52

Generated On: 12 Aug 2021 13:31:43

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input checked="" type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

US3832250

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:43

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3832250 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832250

Form: Participant Creation

Generated On: 12 Aug 2021 13:31:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:05:23
User entered 'US3832250'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 19:29:24

US3832250

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:05:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:05

US3832250

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:05:55
User entered '24 AUG 2020'	RWS_ENDPOINT	24 Aug 2020 19:29:25
	ENDPOINT (b) (4)	

US3832250

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[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 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:05:55
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:05

US3832250

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'SCRN'	System	24 Aug 2020 19:38:05

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered (b) (6) 1992'	RWS_ENDPOINT	24 Aug 2020 19:29:26
	ENDPOINT (b) (4)	

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '28'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'YEARS'	System	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '28'	System	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered 'Female (F)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered 'l'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:06
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:15

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'Aug 2020'	System	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '2020'	System	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered 'Amendment 2 (2)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:27

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 19:29:25

US3832250

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'I'	System	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:31:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:27
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:34

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:45
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:41:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:41:35
Data point term sent to Coder	System	24 Aug 2020 19:40:26
User entered 'Cholecystitis'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:48
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:50
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:06:52
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:19:52
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration' answered with 'Verified and Updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 13:34:47
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 13:34:30
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:37:23
Query 'Per DM CLR: Please review the status of this MH as the duration of ongoing is unexpected for this condition. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:36:56
User opened query 'Per DM CLR: Please review the status of this MH as the duration of ongoing is unexpected for this condition. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:32:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:06:56
User entered 'UN UNK 2015' reason for change:	Alyssa-Kay Peay (b) (4)	09 Oct 2020 13:34:30
Data Entry Error	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:57
	(b) (4)	

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:00
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'Jan 2015'	System	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '2015'	System	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'Jan 2015'	System	09 Oct 2020 13:34:30
User entered empty.	System	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '2015'	System	09 Oct 2020 13:34:30
User entered empty.	System	24 Aug 2020 19:39:57

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:07:06
User closed query 'Per DM CLR: Please note, stop date of MH = UN UNK 2005. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:20:00
Query 'Per DM CLR: Please note, stop date of MH = UN UNK 2005. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' answered with 'Verified and updated medical history' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Oct 2020 13:39:12
User opened query 'Per DM CLR: Please note, stop date of MH = UN UNK 2005. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:38:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:41:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:41:37
Data point term sent to Coder	System	24 Aug 2020 19:40:27
User entered 'Appendicitis'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:20
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:24
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:26
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:28
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:07:32
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'Jan 2005'	System	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '2005'	System	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'Jan 2005'	System	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '2005'	System	24 Aug 2020 19:40:12

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered '15:42'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '24 Aug 2020 15:42'	System	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered '162.6' cm	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14
DataPoint set to visible.	System	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered '85.3' kg	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14
DataPoint set to visible.	System	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
Amendment Manager: User entered '32.26324'	System	17 Sep 2020 00:21:50
User entered '32.3'	System	24 Aug 2020 20:39:14
DataPoint set to visible.	System	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'kg/m2'	System	24 Aug 2020 20:39:14
DataPoint set to visible.	System	24 Aug 2020 19:38:30

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:36:42
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:42:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:42:22
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:24:40
User entered '98.0' F	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'please delete' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:36:46
Query 'please delete' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:39
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:22
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:24:49
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 20:39:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:14
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:43
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:36:50
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:42:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:42:22
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:24:56
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 20:39:41
User entered '77' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:14
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'bpm'	System	24 Aug 2020 20:39:41
User entered empty.	System	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:36:56
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:22
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:25:02
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 20:39:41
User entered '16' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:14
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'breaths/min'	System	24 Aug 2020 20:39:41
User entered empty.	System	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:37:00
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:42:22
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:25:10
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 20:39:41
User entered '106' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:14
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'mmHg'	System	24 Aug 2020 20:39:41
User entered empty.	System	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:10:43
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:37:03
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:43:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:42:22
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:25:18
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Aug 2020 20:39:41
User entered '71' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 20:39:14
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'mmHg'	System	24 Aug 2020 20:39:41
User entered empty.	System	24 Aug 2020 20:39:14

US3832250

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39

US3832250

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:25

US3832250

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:10:32
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:25

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:12
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:40:40

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:23
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:24
User entered 'Urine (URINE)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:27
User entered 'Negative (NEGATIVE)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:41:43
User closed query 'per source, FSH was not collected. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:41:39
Query 'per source, FSH was not collected. please confirm and update' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:34:46
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:34:31
User opened query 'per source, FSH was not collected. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:17:53
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:33:25
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 16:31:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 16:31:21
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:32:09
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 13:41:53
User closed query 'this is for FSH - please delete' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:41:47
Query 'this is for FSH - please delete' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4)	16 Dec 2020 01:34:53
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	16 Dec 2020 01:34:31
User opened query 'this is for FSH - please delete' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:18:17
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 13:42:03
User closed query 'this is for FSH - please delete' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:41:58
Query 'this is for FSH - please delete' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4)	16 Dec 2020 01:34:59
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	16 Dec 2020 01:34:31
User opened query 'this is for FSH - please delete' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:18:25
User entered '15:33'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered empty.	System	16 Dec 2020 01:34:31
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 20:40:24

US3832250

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

US3832250

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:41:19

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
User closed query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:46:04
Query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:08:35
User opened query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:00:09
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:11:38
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 21:08:31
User entered '0'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
User closed query 'please untick. This section is for living conditions only. (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:46:07
Query 'please untick. This section is for living conditions only. answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:08:40
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:08:31
User opened query 'please untick. This section is for living conditions only. (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:00:30
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:41:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:11:38
User closed query 'please delete. This section is for living conditions only. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:46:11
Query 'please delete. This section is for living conditions only. ' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:08:44
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:08:31
User opened query 'please delete. This section is for living conditions only. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:00:58
User entered 'Children in the household are likely to go back to school in person this year'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:41:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:46

US3832250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:32
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:46

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:32
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:40:46

US3832250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'VISIT1'	System	24 Aug 2020 20:40:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:33:41
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:04:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:33:41
User entered '106306'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:04:53

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 20:04:53

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:20

US3832250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:33:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:20

US3832250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:43

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
User closed query 'please complete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:57
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:47:52
Query 'please complete' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4)	29 Nov 2020 19:06:37
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	29 Nov 2020 19:06:31
User opened query 'please complete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:19:29
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:44:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:49:59
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:03
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:38
User entered '162.6' cm	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:50:01
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:08
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:41
User entered '85.3' kg	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:49:59
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:03
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:38
User entered '162.6' cm	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:50:01
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:08
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:41
User entered '85.3' kg	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '15:42'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '24 Aug 2020 15:42'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '98.0' F	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '77'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'bpm'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '16'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'breaths/min'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '106'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '71'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:49:59
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:03
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:38
User entered '162.6' cm	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:20:22
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:50:01
Query 'Per eCRF guidelines, please enter ND.'	Danyel Johnson (b) (4)	12 Nov 2020 20:59:08
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:58:50
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:13:41
User entered '85.3' kg	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44
	(b) (4)	

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '17:06'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '24 Aug 2020 17:06'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '97.9' F	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '77'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'bpm'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '15'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'breaths/min'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '114'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:22
User entered '79'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	24 Aug 2020 21:15:44

US3832250

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	25 Nov 2020 18:26:41
User closed query 'Per eCRF guidelines, please enter No.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:40:53
Query 'Per eCRF guidelines, please enter No.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:46:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 20:46:14
User opened query 'Per eCRF guidelines, please enter No.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:22:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:45

US3832250

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:41
User closed query 'please delete date' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:40:55
Query 'please delete date' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:46:21
User entered empty; reason for change Data Entry Error	(b) (4) Danyel Johnson (b) (4)	12 Nov 2020 20:46:14
User opened query 'please delete date' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:23:15
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:41:45

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:33:10
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 16:51:34
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at VID1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:46:46
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:34
User entered '24 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:34
User entered 'Urine (URINE)'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22
	(b) (4)	

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:34
User entered 'Negative (NEGATIVE)'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User closed query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:08:03
Query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' answered with 'updated per query ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 19:08:36
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 19:08:27
User opened query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:33:15
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 16:51:34
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:46:31
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:31:58
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:42:22

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:34
User entered '24 Aug 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22
	(b) (4)	

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:27:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 16:51:34
User entered '15:33'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:22
	(b) (4)	

US3832250

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	21 Oct 2020 16:51:34
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 20:42:22

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered '16:35'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '24 Aug 2020 16:35'	System	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:18
User entered 'ONCE'	System	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 20:42:55

US3832250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:33
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:55:39

US3832250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:33
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:55:39

US3832250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:33
User entered '15:55'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:55:39

US3832250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '24 Aug 2020 15:55'	System	24 Aug 2020 20:55:39

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:40
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:40
User entered '15:50'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '24 Aug 2020 15:50'	System	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:28:40
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:57:35
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:28:40
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:57:35
User entered '15:50'	(b) (4) Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:07
	(b) (4)	

US3832250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	11 Nov 2020 19:57:35
User entered '24 Aug 2020 15:50'	System	24 Aug 2020 20:56:07

US3832250

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:46
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 20:56:14

US3832250

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	24 Aug 2020 20:56:14

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:22', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6ed22904-97be-44e3-bd98-0dcc2ab59c93'	System	24 Aug 2020 21:07:40
User entered 'Yes (Y)'	System	24 Aug 2020 21:07:40

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:32', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6ed22904-97be-44e3-bd98-0dcc2ab59c93' User entered '97.9'	System	24 Aug 2020 21:07:40
	System	24 Aug 2020 21:07:40

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:35', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6ed22904-97be-44e3-bd98-0dcc2ab59c93'	System	24 Aug 2020 21:07:40
User entered 'No (N)'	System	24 Aug 2020 21:07:40

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:38', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6ed22904-97be-44e3-bd98-0dcc2ab59c93'	System	24 Aug 2020 21:07:40
User entered '24 Aug 2020 17:07'	System	24 Aug 2020 21:07:40

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 16:55'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 19:25'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:24:41', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9b7e2010-1beb-4c12-8ce9-0442cfaa8eb8' User entered 'Yes (Y)'	System	25 Aug 2020 00:24:55
	System	25 Aug 2020 00:24:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:24:45', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9b7e2010-1beb-4c12-8ce9-0442cfaa8eb8' User entered '99.3'	System	25 Aug 2020 00:24:55
	System	25 Aug 2020 00:24:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:24:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9b7e2010-1beb-4c12-8ce9-0442cfaa8eb8'	System	25 Aug 2020 00:24:55
User entered 'No (N)'	System	25 Aug 2020 00:24:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:24:51', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9b7e2010-1beb-4c12-8ce9-0442cfaa8eb8'	System	25 Aug 2020 00:24:55
User entered '24 Aug 2020 20:24'	System	25 Aug 2020 00:24:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 20:20'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 2'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:38', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '8b0b0daa-5e19-4219-be1f-be4c43f141b7'	System	25 Aug 2020 16:04:15
User entered 'Yes (Y)'	System	25 Aug 2020 16:04:15

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:44', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '8b0b0daa-5e19-4219-be1f-be4c43f141b7' User entered '98.1'	System	25 Aug 2020 16:04:15
	System	25 Aug 2020 16:04:15

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:47', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '8b0b0daa-5e19-4219-be1f-be4c43f141b7'	System	25 Aug 2020 16:04:15
User entered 'No (N)'	System	25 Aug 2020 16:04:15

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:49', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '8b0b0daa-5e19-4219-be1f-be4c43f141b7'	System	25 Aug 2020 16:04:15
User entered '25 Aug 2020 12:03'	System	25 Aug 2020 16:04:15

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 3'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:07:19', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9331ea2d-858a-4c05-bce0-6a507bbe52df' User entered 'Yes (Y)'	System	26 Aug 2020 16:07:31
	System	26 Aug 2020 16:07:31

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:07:26', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9331ea2d-858a-4c05-bce0-6a507bbe52df' User entered '99.0'	System	26 Aug 2020 16:07:31
	System	26 Aug 2020 16:07:31

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:07:12', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9331ea2d-858a-4c05-bce0-6a507bbe52df' User entered 'No (N)'	System	26 Aug 2020 16:07:31
	System	26 Aug 2020 16:07:31

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:07:28', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9331ea2d-858a-4c05-bce0-6a507bbe52df' User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:31
	System	26 Aug 2020 16:07:31

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 4'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:39', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3f2d627e-3673-4df4-af9e-ac25c49ba10a' User entered 'Yes (Y)'	System	27 Aug 2020 16:09:52
	System	27 Aug 2020 16:09:52

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:44', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3f2d627e-3673-4df4-af9e-ac25c49ba10a' User entered '98.3'	System	27 Aug 2020 16:09:52
	System	27 Aug 2020 16:09:52

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:46', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3f2d627e-3673-4df4-af9e-ac25c49ba10a'	System	27 Aug 2020 16:09:52
User entered 'No (N)'	System	27 Aug 2020 16:09:52

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3f2d627e-3673-4df4-af9e-ac25c49ba10a' User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:09:52
	System	27 Aug 2020 16:09:52

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 5'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:40', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1675c6bc-1a80-45e3-a05b-9c0c386cd3f6'	System	28 Aug 2020 18:17:54
User entered 'Yes (Y)'	System	28 Aug 2020 18:17:54

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:46', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1675c6bc-1a80-45e3-a05b-9c0c386cd3f6' User entered '99.1'	System	28 Aug 2020 18:17:54
	System	28 Aug 2020 18:17:54

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1675c6bc-1a80-45e3-a05b-9c0c386cd3f6'	System	28 Aug 2020 18:17:54
User entered 'No (N)'	System	28 Aug 2020 18:17:54

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:50', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1675c6bc-1a80-45e3-a05b-9c0c386cd3f6' User entered '28 Aug 2020 14:17'	System	28 Aug 2020 18:17:54
	System	28 Aug 2020 18:17:54

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 6'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:08', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'bdaa7f64-a2dc-43bb-b1e9-bae00458fadc' User entered 'Yes (Y)'	System	29 Aug 2020 17:20:19
	System	29 Aug 2020 17:20:19

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:12', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'bdaa7f64-a2dc-43bb-b1e9-bae00458fadc' User entered '99.8'	System	29 Aug 2020 17:20:19
	System	29 Aug 2020 17:20:19

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:14', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'bdaa7f64-a2dc-43bb-b1e9-bae00458fadc'	System	29 Aug 2020 17:20:19
User entered 'No (N)'	System	29 Aug 2020 17:20:19

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:16', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'bdaa7f64-a2dc-43bb-b1e9-bae00458fadc' User entered '29 Aug 2020 13:20'	System	29 Aug 2020 17:20:19
	System	29 Aug 2020 17:20:19

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 7'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:19:30', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '43bab1f0-f013-4d59-9ad2-8997bc46cd89'	System	30 Aug 2020 16:19:59
User entered 'Yes (Y)'	System	30 Aug 2020 16:19:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:19:35', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '43bab1f0-f013-4d59-9ad2-8997bc46cd89' User entered '98.2'	System	30 Aug 2020 16:19:59
	System	30 Aug 2020 16:19:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:19:52', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '43bab1f0-f013-4d59-9ad2-8997bc46cd89'	System	30 Aug 2020 16:19:59
User entered 'No (N)'	System	30 Aug 2020 16:19:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:19:56', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '43bab1f0-f013-4d59-9ad2-8997bc46cd89'	System	30 Aug 2020 16:19:59
User entered '30 Aug 2020 12:19'	System	30 Aug 2020 16:19:59

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:54', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c92983ce-d103-45c6-9699-5a62b4032474'	System	24 Aug 2020 21:08:12
User entered 'None (1)'	System	24 Aug 2020 21:08:12

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:07:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c92983ce-d103-45c6-9699-5a62b4032474'	System	24 Aug 2020 21:08:12
User entered 'No (N)'	System	24 Aug 2020 21:08:12

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c92983ce-d103-45c6-9699-5a62b4032474'	System	24 Aug 2020 21:08:12
User entered 'No (N)'	System	24 Aug 2020 21:08:12

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:07', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c92983ce-d103-45c6-9699-5a62b4032474'	System	24 Aug 2020 21:08:12
User entered 'None (1)'	System	24 Aug 2020 21:08:12

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:10', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c92983ce-d103-45c6-9699-5a62b4032474'	System	24 Aug 2020 21:08:12
User entered '24 Aug 2020 17:08'	System	24 Aug 2020 21:08:12

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 16:55'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 19:25'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:25', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3574b0be-7ad0-4a80-af43-846ef2e16ee2'	System	25 Aug 2020 00:25:46
User entered 'None (1)'	System	25 Aug 2020 00:25:46

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:27', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3574b0be-7ad0-4a80-af43-846ef2e16ee2'	System	25 Aug 2020 00:25:46
User entered 'No (N)'	System	25 Aug 2020 00:25:46

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:34', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3574b0be-7ad0-4a80-af43-846ef2e16ee2'	System	25 Aug 2020 00:25:46
User entered 'No (N)'	System	25 Aug 2020 00:25:46

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:41', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3574b0be-7ad0-4a80-af43-846ef2e16ee2'	System	25 Aug 2020 00:25:46
User entered 'None (1)'	System	25 Aug 2020 00:25:46

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:43', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3574b0be-7ad0-4a80-af43-846ef2e16ee2'	System	25 Aug 2020 00:25:46
User entered '24 Aug 2020 20:25'	System	25 Aug 2020 00:25:46

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 20:20'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 2'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a7f39665-2620-423c-82ad-dea24262cdae'	System	25 Aug 2020 16:03:18
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 16:03:18

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:04', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a7f39665-2620-423c-82ad-dea24262cdae'	System	25 Aug 2020 16:03:18
User entered 'No (N)'	System	25 Aug 2020 16:03:18

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:15', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a7f39665-2620-423c-82ad-dea24262cdae'	System	25 Aug 2020 16:03:18
User entered 'No (N)'	System	25 Aug 2020 16:03:18

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:28', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a7f39665-2620-423c-82ad-dea24262cdae'	System	25 Aug 2020 16:03:18
User entered 'None (1)'	System	25 Aug 2020 16:03:18

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:38', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a7f39665-2620-423c-82ad-dea24262cdae' User entered '25 Aug 2020 12:02'	System	25 Aug 2020 16:03:18
	System	25 Aug 2020 16:03:18

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 3'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:04:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '505d6dc1-95e2-4359-a6ce-b60186241aef'	System	26 Aug 2020 16:05:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Aug 2020 16:05:40

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:15', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '505d6dc1-95e2-4359-a6ce-b60186241aef' User entered 'No (N)'	System	26 Aug 2020 16:05:40
	System	26 Aug 2020 16:05:40

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:22', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '505d6dc1-95e2-4359-a6ce-b60186241aef'	System	26 Aug 2020 16:05:40
User entered 'No (N)'	System	26 Aug 2020 16:05:40

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:30', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '505d6dc1-95e2-4359-a6ce-b60186241aef' User entered 'None (1)'	System	26 Aug 2020 16:05:40
	System	26 Aug 2020 16:05:40

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:32', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '505d6dc1-95e2-4359-a6ce-b60186241aef' User entered '26 Aug 2020 12:05'	System	26 Aug 2020 16:05:40
	System	26 Aug 2020 16:05:40

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 4'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:27', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a41c1ea0-da93-4a0d-be49-997067044725'	System	27 Aug 2020 16:09:39
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 16:09:39

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:29', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a41c1ea0-da93-4a0d-be49-997067044725' User entered 'No (N)'	System	27 Aug 2020 16:09:39
	System	27 Aug 2020 16:09:39

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:31', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a41c1ea0-da93-4a0d-be49-997067044725' User entered 'No (N)'	System	27 Aug 2020 16:09:39
	System	27 Aug 2020 16:09:39

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:34', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a41c1ea0-da93-4a0d-be49-997067044725' User entered 'None (1)'	System	27 Aug 2020 16:09:39
	System	27 Aug 2020 16:09:39

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:36', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a41c1ea0-da93-4a0d-be49-997067044725' User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:09:39
	System	27 Aug 2020 16:09:39

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 5'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:53', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '67bd2e27-2782-42a2-9f16-44963c0e55a8' User entered 'None (1)'	System	28 Aug 2020 18:18:04
	System	28 Aug 2020 18:18:04

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:55', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '67bd2e27-2782-42a2-9f16-44963c0e55a8' User entered 'No (N)'	System	28 Aug 2020 18:18:04
	System	28 Aug 2020 18:18:04

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '67bd2e27-2782-42a2-9f16-44963c0e55a8'	System	28 Aug 2020 18:18:04
User entered 'No (N)'	System	28 Aug 2020 18:18:04

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:17:58', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '67bd2e27-2782-42a2-9f16-44963c0e55a8' User entered 'None (1)'	System	28 Aug 2020 18:18:04
	System	28 Aug 2020 18:18:04

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '67bd2e27-2782-42a2-9f16-44963c0e55a8' User entered '28 Aug 2020 14:18'	System	28 Aug 2020 18:18:04
	System	28 Aug 2020 18:18:04

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 6'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:21', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '14586bb9-66bc-4dfe-ae25-400d2836d267'	System	29 Aug 2020 17:20:35
User entered 'None (1)'	System	29 Aug 2020 17:20:35

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:23', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '14586bb9-66bc-4dfe-ae25-400d2836d267'	System	29 Aug 2020 17:20:35
User entered 'No (N)'	System	29 Aug 2020 17:20:35

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:25', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '14586bb9-66bc-4dfe-ae25-400d2836d267'	System	29 Aug 2020 17:20:35
User entered 'No (N)'	System	29 Aug 2020 17:20:35

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:26', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '14586bb9-66bc-4dfe-ae25-400d2836d267'	System	29 Aug 2020 17:20:35
User entered 'None (1)'	System	29 Aug 2020 17:20:35

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:34', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '14586bb9-66bc-4dfe-ae25-400d2836d267'	System	29 Aug 2020 17:20:35
User entered '29 Aug 2020 13:20'	System	29 Aug 2020 17:20:35

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 7'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:14:55', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee94d201-a601-4e82-86e3-93eeb64a9aab'	System	30 Aug 2020 16:15:05
User entered 'None (1)'	System	30 Aug 2020 16:15:05

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:14:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee94d201-a601-4e82-86e3-93eeb64a9aab'	System	30 Aug 2020 16:15:05
User entered 'No (N)'	System	30 Aug 2020 16:15:05

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:14:59', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee94d201-a601-4e82-86e3-93eeb64a9aab'	System	30 Aug 2020 16:15:05
User entered 'No (N)'	System	30 Aug 2020 16:15:05

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:01', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee94d201-a601-4e82-86e3-93eeb64a9aab'	System	30 Aug 2020 16:15:05
User entered 'None (1)'	System	30 Aug 2020 16:15:05

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:03', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee94d201-a601-4e82-86e3-93eeb64a9aab'	System	30 Aug 2020 16:15:05
User entered '30 Aug 2020 12:15'	System	30 Aug 2020 16:15:05

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:17', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:20', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:22', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:25', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:27', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:30', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'None (0)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:38', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered 'No (N)'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T17:08:40', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1af5ff6d-5ef2-4a17-acbc-8b26925727db' User entered '24 Aug 2020 17:08'	System	24 Aug 2020 21:08:42
	System	24 Aug 2020 21:08:42

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 16:55'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 19:25'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:49', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:53', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:25:58', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:26:02', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:26:06', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:26:13', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'None (0)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:26:21', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered 'No (N)'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-24T20:26:23', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '4994f8c8-4424-494d-b3e5-1bebf5aa508a' User entered '24 Aug 2020 20:26'	System	25 Aug 2020 00:26:25
	System	25 Aug 2020 00:26:25

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '24 Aug 2020 20:20'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 2'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:44', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b' User entered 'None (0)'	System	25 Aug 2020 16:03:51
	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:47', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b'	System	25 Aug 2020 16:03:51
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:53', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b'	System	25 Aug 2020 16:03:51
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:02:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b' User entered 'None (0)'	System	25 Aug 2020 16:03:51
	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b' User entered 'None (0)'	System	25 Aug 2020 16:03:51
	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:04', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b'	System	25 Aug 2020 16:03:51
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:12', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b'	System	25 Aug 2020 16:03:51
User entered 'No (N)'	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-25T12:03:14', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'dedef2fc-cef7-4318-908c-0ee1a27dc39b'	System	25 Aug 2020 16:03:51
User entered '25 Aug 2020 12:03'	System	25 Aug 2020 16:03:51

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 3'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:38', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered 'None (0)'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:40', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1'	System	26 Aug 2020 16:06:05
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1'	System	26 Aug 2020 16:06:05
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:52', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered 'None (0)'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:55', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered 'None (0)'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:05:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered 'None (0)'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:06:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered 'No (N)'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-26T12:06:03', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '01a07fac-bae2-45cf-911d-043f1a80d5f1' User entered '26 Aug 2020 12:06'	System	26 Aug 2020 16:06:05
	System	26 Aug 2020 16:06:05

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 4'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:06', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered 'None (0)'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:09', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered 'None (0)'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:10', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered 'None (0)'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:11', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6' User entered 'None (0)'	System	27 Aug 2020 16:09:23
	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:13', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6' User entered 'None (0)'	System	27 Aug 2020 16:09:23
	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:14', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered 'None (0)'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:16', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered 'No (N)'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-27T12:09:19', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9097c6ed-3048-4973-8940-d420e00a9eb6'	System	27 Aug 2020 16:09:23
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:09:23

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 5'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:04', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5' User entered 'None (0)'	System	28 Aug 2020 18:18:38
	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:06', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5'	System	28 Aug 2020 18:18:38
User entered 'No interference with activity (1)'	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:10', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5' User entered 'None (0)'	System	28 Aug 2020 18:18:38
	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:28', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5' User entered 'None (0)'	System	28 Aug 2020 18:18:38
	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:29', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5' User entered 'None (0)'	System	28 Aug 2020 18:18:38
	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:31', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5' User entered 'None (0)'	System	28 Aug 2020 18:18:38
	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:33', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5'	System	28 Aug 2020 18:18:38
User entered 'No (N)'	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-28T14:18:35', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b2de68de-00e2-4a2e-9271-6c3508c8dbf5'	System	28 Aug 2020 18:18:38
User entered '28 Aug 2020 14:18'	System	28 Aug 2020 18:18:38

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 6'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:39', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:40', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:42', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:44', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:45', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:47', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'None (0)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered 'No (N)'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-29T13:20:50', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ed94fa23-0961-42fd-88d8-03d9debce21b' User entered '29 Aug 2020 13:20'	System	29 Aug 2020 17:20:53
	System	29 Aug 2020 17:20:53

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 7'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:10', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40'	System	30 Aug 2020 16:15:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:17', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40'	System	30 Aug 2020 16:15:35
User entered 'Some interference with activity (2)'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:19', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40' User entered 'None (0)'	System	30 Aug 2020 16:15:35
	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:22', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40' User entered 'None (0)'	System	30 Aug 2020 16:15:35
	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:24', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40' User entered 'None (0)'	System	30 Aug 2020 16:15:35
	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:27', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40'	System	30 Aug 2020 16:15:35
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:29', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40' User entered 'No (N)'	System	30 Aug 2020 16:15:35
	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-30T12:15:31', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '7af7d678-9482-4830-ace1-e628e87a0d40' User entered '30 Aug 2020 12:15'	System	30 Aug 2020 16:15:35
	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	30 Aug 2020 16:15:35
User entered 'Day 8'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:27', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '788cf2cc-7be5-4993-bad1-aecf6350bddb'	System	31 Aug 2020 16:20:31
User entered 'No interference with activity (1)'	System	31 Aug 2020 16:20:31

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:30', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '788cf2cc-7be5-4993-bad1-aecf6350bddb'	System	31 Aug 2020 16:20:31
User entered '31 Aug 2020 12:09'	System	31 Aug 2020 16:20:31

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	30 Aug 2020 16:15:35
User entered 'Day 9'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-09-01T13:44:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd1f7969e-ebca-4e4b-b6d3-dd3cca48b83b' User entered 'None (0)'	System	01 Sep 2020 17:44:07
	System	01 Sep 2020 17:44:07

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-09-01T13:44:02', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd1f7969e-ebca-4e4b-b6d3-dd3cca48b83b' User entered '01 Sep 2020 13:44'	System	01 Sep 2020 17:44:07
	System	01 Sep 2020 17:44:07

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	30 Aug 2020 16:15:35
User entered 'Day 8'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:35', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '26941a8b-a370-4fb3-946f-2d9d749287da' User entered 'None (0)'	System	31 Aug 2020 16:20:31
	System	31 Aug 2020 16:20:31

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:37', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '26941a8b-a370-4fb3-946f-2d9d749287da' User entered '31 Aug 2020 12:09'	System	31 Aug 2020 16:20:31
	System	31 Aug 2020 16:20:31

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	30 Aug 2020 16:15:35
User entered 'Day 8'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:40', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b01cf223-430c-4f13-b1f6-80bd82de2b99'	System	31 Aug 2020 16:20:39
User entered 'None (0)'	System	31 Aug 2020 16:20:39

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:42', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b01cf223-430c-4f13-b1f6-80bd82de2b99'	System	31 Aug 2020 16:20:39
User entered '31 Aug 2020 12:09'	System	31 Aug 2020 16:20:39

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	30 Aug 2020 16:15:35
User entered 'Day 8'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:46', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '98b82480-37cb-4f4b-b46e-b512f4002aaf'	System	31 Aug 2020 16:20:42
User entered 'No (N)'	System	31 Aug 2020 16:20:42

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAACB3C3-8CE6-4962-BA0F-12311F85EEB7)', Time: '2020-08-31T12:09:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '98b82480-37cb-4f4b-b46e-b512f4002aaf'	System	31 Aug 2020 16:20:42
User entered '31 Aug 2020 12:09'	System	31 Aug 2020 16:20:42

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 16:15:35

US3832250

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:31:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 16:15:35

US3832250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:56
User entered 'Yes (Y)'	Emma Partin (b) (4)	31 Aug 2020 19:53:01

US3832250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:56
User entered '31 Aug 2020'	Emma Partin (b) (4)	31 Aug 2020 19:53:01

US3832250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:56
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	31 Aug 2020 19:53:01

US3832250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:28:56
User entered empty.	Emma Partin (b) (4)	31 Aug 2020 19:53:01

US3832250

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:02
User entered 'Yes (Y)'	Emma Partin (b) (4)	31 Aug 2020 19:53:07

US3832250

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	31 Aug 2020 19:53:07

US3832250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:08
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	08 Sep 2020 19:33:44

US3832250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:08
User entered '8 Sep 2020'	Alyssa-Kay Peay (b) (4)	08 Sep 2020 19:33:44

US3832250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:08
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	08 Sep 2020 19:33:44

US3832250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:08
User entered empty.	Alyssa-Kay Peay (b) (4)	08 Sep 2020 19:33:44

US3832250

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:13
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	08 Sep 2020 19:33:47

US3832250

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	08 Sep 2020 19:33:47

US3832250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	14 Sep 2020 15:04:31

US3832250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:21
User entered '14 Sep 2020'	Alyssa-Kay Peay (b) (4)	14 Sep 2020 15:04:31

US3832250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:21
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	14 Sep 2020 15:04:31

US3832250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:21
User entered empty.	Alyssa-Kay Peay (b) (4)	14 Sep 2020 15:04:31

US3832250

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	14 Sep 2020 15:04:23

US3832250

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	14 Sep 2020 15:04:23

US3832250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:32:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:40:40

US3832250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:32:52
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:40:40

US3832250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:32:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 10:40:40

US3832250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'VISIT2'	System	22 Sep 2020 10:40:40

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '13:06'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '21 Sep 2020 13:06'	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '97.9' F	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '82'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'bpm'	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'breaths/min'	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '114'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered '78'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 14:34:03
User closed query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:37:08
Query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' answered with 'Subject was not dosed due to pregnancy. No post dose vitals collected ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	03 Nov 2020 19:07:51
User opened query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:24:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:42:06

US3832250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:42:13

US3832250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:32:57
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:42:13

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User closed query 'Per CDM: If pregnancy test is positive and confirmed, it should be recorded on the AE form as IQVIA collects that data.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:34:00
Query 'Per CDM: If pregnancy test is positive and confirmed, it should be recorded on the AE form as IQVIA collects that data.' answered with 'updated per query' (Site from DM).	Emma Partin (b) (4)	22 Oct 2020 18:39:13
User opened query 'Per CDM: If pregnancy test is positive and confirmed, it should be recorded on the AE form as IQVIA collects that data.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:34:17
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) (6)	24 Sep 2020 12:17:50
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 'Confirmed pregnancy test was positive. Pregnancy form submitted on 21/Sep/2020' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 10:43:29
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	22 Sep 2020 10:42:51
User entered 'Positive (POSITIVE)'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 14:34:29
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:34:02
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 20:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 20:08:18
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:32:24
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:29
User entered '13:15'	(b) (4), (b) (6)	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '21 Sep 2020 13:15'	System	22 Sep 2020 10:42:51

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered 'Pregnancy (PREGNANCY)'	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:34:46
User entered empty.	System	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	22 Sep 2020 10:43:46

US3832250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:44:09

US3832250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:45
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:44:09

US3832250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:45
User entered '13:46'	(b) (4), (b) (6)	22 Sep 2020 10:44:09

US3832250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '21 Sep 2020 13:46'	System	22 Sep 2020 10:44:09

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:59
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:35:59
User entered '13:44'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '21 Sep 2020 13:44'	System	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 14:35:59
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:57:55
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4)	06 Jan 2021 14:35:59
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:57:55
User entered '13:44'	(b) (4), (b) (6)	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered empty.	System	11 Nov 2020 19:57:55
User entered '21 Sep 2020 13:44'	System	22 Sep 2020 10:44:33

US3832250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:36:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 10:44:44

US3832250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '1'	System	22 Sep 2020 10:44:44

US3832250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:37:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:09:34

US3832250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:37:45
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:09:34

US3832250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:37:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 21:09:34

US3832250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:37:45
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:09:34

US3832250

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:37:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:09:38

US3832250

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	01 Oct 2020 21:09:38

US3832250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:39:08
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	05 Oct 2020 13:46:14

US3832250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:39:08
User entered '05 Oct 2020'	Alyssa-Kay Peay (b) (4)	05 Oct 2020 13:46:14

US3832250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:39:08
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	05 Oct 2020 13:46:14

US3832250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:39:08
User entered empty.	Alyssa-Kay Peay (b) (4)	05 Oct 2020 13:46:14

US3832250

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:39:13
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	05 Oct 2020 13:46:18

US3832250

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	05 Oct 2020 13:46:18

US3832250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:49:35
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	14 Oct 2020 13:18:47

US3832250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:49:35
User entered '14 Oct 2020'	Alyssa-Kay Peay (b) (4)	14 Oct 2020 13:18:47

US3832250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:49:35
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	14 Oct 2020 13:18:47

US3832250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:49:35
User entered empty.	Alyssa-Kay Peay (b) (4)	14 Oct 2020 13:18:47

US3832250

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:49:41
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	14 Oct 2020 13:18:52

US3832250

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	14 Oct 2020 13:18:52

US3832250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:50:04
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:13:36

US3832250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:50:04
User entered '20 Oct 2020'	Emma Partin (b) (4)	20 Oct 2020 14:13:36

US3832250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 14:50:04
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	20 Oct 2020 14:13:36

US3832250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'VISIT3'	System	20 Oct 2020 14:13:36

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '20 Oct 2020'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '08:38'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '20 Oct 2020 08:38'	System	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '97.9' F	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered 'Oral (Oral)'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '80'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'bpm'	System	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '13'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'breaths/min'	System	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '118'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:06:59
User entered '80'	Emma Partin (b) (4)	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'mmHg'	System	20 Oct 2020 14:16:28

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37

US3832250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37

US3832250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:05
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:16:48

US3832250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:05
User entered '20 Oct 2020'	Emma Partin (b) (4)	20 Oct 2020 14:16:48

US3832250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:23
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:18:07

US3832250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:23
User entered '20 Oct 2020'	Emma Partin (b) (4)	20 Oct 2020 14:18:07

US3832250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:23
User entered '08:52'	Emma Partin (b) (4)	20 Oct 2020 14:18:07

US3832250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered '20 Oct 2020 08:52'	System	20 Oct 2020 14:18:07

US3832250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:33:40
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:07:27
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:18:13

US3832250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	20 Oct 2020 14:18:13

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 64'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-10-26T11:58:02', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '129fbcef-f0b9-4091-8164-aec7b02e291d'	System	26 Oct 2020 15:58:11
User entered 'No (N)'	System	26 Oct 2020 15:58:11

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-10-26T11:58:06', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '129fbcef-f0b9-4091-8164-aec7b02e291d'	System	26 Oct 2020 15:58:11
User entered 'No (N)'	System	26 Oct 2020 15:58:11

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-10-26T11:58:08', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '129fbcef-f0b9-4091-8164-aec7b02e291d'	System	26 Oct 2020 15:58:11
User entered '26 Oct 2020 11:58:08'	System	26 Oct 2020 15:58:11

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 71'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-01T11:40:14', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '58353b00-e29d-4424-9ed1-7996aa58cf65'	System	01 Nov 2020 16:40:23
User entered 'No (N)'	System	01 Nov 2020 16:40:23

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-01T11:40:18', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '58353b00-e29d-4424-9ed1-7996aa58cf65'	System	01 Nov 2020 16:40:23
User entered 'No (N)'	System	01 Nov 2020 16:40:23

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-01T11:40:21', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '58353b00-e29d-4424-9ed1-7996aa58cf65'	System	01 Nov 2020 16:40:23
User entered '01 Nov 2020 11:40:21'	System	01 Nov 2020 16:40:23

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered 'Day 78'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-09T09:43:48', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '660e64ed-b5db-4846-99f4-8e057e8a6aea'	System	09 Nov 2020 14:43:57
User entered 'No (N)'	System	09 Nov 2020 14:43:57

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-09T09:43:53', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '660e64ed-b5db-4846-99f4-8e057e8a6aea'	System	09 Nov 2020 14:43:57
User entered 'No (N)'	System	09 Nov 2020 14:43:57

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-11-09T09:43:55', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '660e64ed-b5db-4846-99f4-8e057e8a6aea'	System	09 Nov 2020 14:43:57
User entered '09 Nov 2020 09:43:55'	System	09 Nov 2020 14:43:57

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 20:42:55

US3832250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:40:07
Data entry locked.	System	24 Aug 2020 20:42:55
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 20:42:55

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-03T19:29:18', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3364161b-8d11-444c-8a8b-c147975ef1da'	System	04 Dec 2020 00:29:25
User entered 'No (N)'	System	04 Dec 2020 00:29:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-03T19:29:21', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3364161b-8d11-444c-8a8b-c147975ef1da'	System	04 Dec 2020 00:29:25
User entered 'No (N)'	System	04 Dec 2020 00:29:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-03T19:29:24', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '3364161b-8d11-444c-8a8b-c147975ef1da'	System	04 Dec 2020 00:29:25
User entered '03 Dec 2020 19:29:24'	System	04 Dec 2020 00:29:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-09T00:01:57', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e46010a0-4d3f-4758-8d2a-20d454a13fe1'	System	09 Dec 2020 05:02:09
User entered 'No (N)'	System	09 Dec 2020 05:02:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-09T00:02:02', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e46010a0-4d3f-4758-8d2a-20d454a13fe1'	System	09 Dec 2020 05:02:09
User entered 'No (N)'	System	09 Dec 2020 05:02:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-09T00:02:05', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e46010a0-4d3f-4758-8d2a-20d454a13fe1'	System	09 Dec 2020 05:02:09
User entered '09 Dec 2020 00:02:05'	System	09 Dec 2020 05:02:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-17T09:00:05', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '81afb3dd-1a23-498b-9058-1d687857e1a5'	System	17 Dec 2020 14:00:16
User entered 'No (N)'	System	17 Dec 2020 14:00:16

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-17T09:00:08', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '81afb3dd-1a23-498b-9058-1d687857e1a5'	System	17 Dec 2020 14:00:16
User entered 'No (N)'	System	17 Dec 2020 14:00:16

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-17T09:00:10', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '81afb3dd-1a23-498b-9058-1d687857e1a5'	System	17 Dec 2020 14:00:16
User entered '17 Dec 2020 09:00:10'	System	17 Dec 2020 14:00:16

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-23T00:02:14', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6516f9d0-47c0-4e92-be8d-a7d3b43bfef2'	System	23 Dec 2020 05:02:53
User entered 'No (N)'	System	23 Dec 2020 05:02:53

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-23T00:02:17', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6516f9d0-47c0-4e92-be8d-a7d3b43bfef2'	System	23 Dec 2020 05:02:53
User entered 'No (N)'	System	23 Dec 2020 05:02:53

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-23T00:02:19', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '6516f9d0-47c0-4e92-be8d-a7d3b43bfef2'	System	23 Dec 2020 05:02:53
User entered '23 Dec 2020 00:02:19'	System	23 Dec 2020 05:02:53

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-31T09:50:51', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '69b273a2-8d3f-46df-a755-e1b840801efc'	System	31 Dec 2020 14:51:07
User entered 'No (N)'	System	31 Dec 2020 14:51:07

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-31T09:51:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '69b273a2-8d3f-46df-a755-e1b840801efc'	System	31 Dec 2020 14:51:07
User entered 'No (N)'	System	31 Dec 2020 14:51:07

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2020-12-31T09:51:02', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '69b273a2-8d3f-46df-a755-e1b840801efc' User entered '31 Dec 2020 09:51:02'	System	31 Dec 2020 14:51:07
	System	31 Dec 2020 14:51:07

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-14T11:21:58', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9dc2d6c0-160b-4fc1-af42-f3a6c9938936'	System	14 Jan 2021 16:22:08
User entered 'No (N)'	System	14 Jan 2021 16:22:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-14T11:22:01', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9dc2d6c0-160b-4fc1-af42-f3a6c9938936'	System	14 Jan 2021 16:22:08
User entered 'No (N)'	System	14 Jan 2021 16:22:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-14T11:22:03', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9dc2d6c0-160b-4fc1-af42-f3a6c9938936'	System	14 Jan 2021 16:22:08
User entered '14 Jan 2021 11:22:03'	System	14 Jan 2021 16:22:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-20T09:57:01', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1d63c628-c41e-41f7-b4a4-480215e233e6'	System	20 Jan 2021 14:57:08
User entered 'No (N)'	System	20 Jan 2021 14:57:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-20T09:57:03', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1d63c628-c41e-41f7-b4a4-480215e233e6'	System	20 Jan 2021 14:57:08
User entered 'No (N)'	System	20 Jan 2021 14:57:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46b94cf64dd79f4e)', Time: '2021-01-20T09:57:06', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '1d63c628-c41e-41f7-b4a4-480215e233e6'	System	20 Jan 2021 14:57:08
User entered '20 Jan 2021 09:57:06'	System	20 Jan 2021 14:57:08

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-10T09:25:23', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '52402f57-bad1-4e73-b441-cc16ba59e9b8' User entered 'No (N)'	System	10 Feb 2021 14:25:30
	System	10 Feb 2021 14:25:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-10T09:25:25', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '52402f57-bad1-4e73-b441-cc16ba59e9b8' User entered 'No (N)'	System	10 Feb 2021 14:25:30
	System	10 Feb 2021 14:25:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-10T09:25:28', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '52402f57-bad1-4e73-b441-cc16ba59e9b8' User entered '10 Feb 2021 09:25:28'	System	10 Feb 2021 14:25:30
	System	10 Feb 2021 14:25:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-17T04:16:47', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a866bf1b-a6b6-46f3-94c5-3b7892d46393'	System	17 Feb 2021 09:16:54
User entered 'No (N)'	System	17 Feb 2021 09:16:54

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-17T04:16:49', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a866bf1b-a6b6-46f3-94c5-3b7892d46393'	System	17 Feb 2021 09:16:54
User entered 'No (N)'	System	17 Feb 2021 09:16:54

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-17T04:16:53', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'a866bf1b-a6b6-46f3-94c5-3b7892d46393'	System	17 Feb 2021 09:16:54
User entered '17 Feb 2021 04:16:53'	System	17 Feb 2021 09:16:54

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-24T10:34:29', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b300a191-e389-4ae6-9cdf-3c6ac1024525' User entered 'No (N)'	System	24 Feb 2021 15:34:36

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-24T10:34:31', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b300a191-e389-4ae6-9cdf-3c6ac1024525'	System	24 Feb 2021 15:34:36
User entered 'No (N)'	System	24 Feb 2021 15:34:36

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-02-24T10:34:33', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'b300a191-e389-4ae6-9cdf-3c6ac1024525' User entered '24 Feb 2021 10:34:33'	System	24 Feb 2021 15:34:36
	System	24 Feb 2021 15:34:36

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-03T08:25:01-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '243f1bf7-1066-466e-b44f-321d433b52a7'	System	03 Mar 2021 13:25:09
User entered 'No (N)'	System	03 Mar 2021 13:25:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-03T08:25:02-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '243f1bf7-1066-466e-b44f-321d433b52a7'	System	03 Mar 2021 13:25:09
User entered 'No (N)'	System	03 Mar 2021 13:25:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-03T08:25:04-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '243f1bf7-1066-466e-b44f-321d433b52a7'	System	03 Mar 2021 13:25:09
User entered '03 Mar 2021 13:25:04'	System	03 Mar 2021 13:25:09

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-10T09:37:54-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd42dbe76-8e04-4f91-9f56-838e76cf8846'	System	10 Mar 2021 14:38:05
User entered 'No (N)'	System	10 Mar 2021 14:38:05

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-10T09:37:55-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd42dbe76-8e04-4f91-9f56-838e76cf8846'	System	10 Mar 2021 14:38:05
User entered 'No (N)'	System	10 Mar 2021 14:38:05

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-10T09:37:57-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd42dbe76-8e04-4f91-9f56-838e76cf8846' User entered '10 Mar 2021 09:37:57'	System	10 Mar 2021 14:38:05
	System	10 Mar 2021 14:38:05

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-17T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2b809176-934c-40ae-8c3e-a182bf451825'	System	17 Mar 2021 04:03:27
User entered 'No (N)'	System	17 Mar 2021 04:03:27

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-17T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2b809176-934c-40ae-8c3e-a182bf451825'	System	17 Mar 2021 04:03:27
User entered 'No (N)'	System	17 Mar 2021 04:03:27

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-17T00:02:29-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2b809176-934c-40ae-8c3e-a182bf451825'	System	17 Mar 2021 04:03:27
User entered '17 Mar 2021 00:02:29'	System	17 Mar 2021 04:03:27

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-24T18:29:23-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e775a127-40f1-4fb5-ab38-090e71bef461'	System	24 Mar 2021 22:29:30
User entered 'No (N)'	System	24 Mar 2021 22:29:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-24T18:29:25-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e775a127-40f1-4fb5-ab38-090e71bef461'	System	24 Mar 2021 22:29:30
User entered 'No (N)'	System	24 Mar 2021 22:29:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-24T18:29:27-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'e775a127-40f1-4fb5-ab38-090e71bef461' User entered '24 Mar 2021 18:29:27'	System	24 Mar 2021 22:29:30
	System	24 Mar 2021 22:29:30

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-03-31T08:50:03-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee136132-7646-496e-a11e-a9652a1f0c0e' User entered 'No (N)'	System	31 Mar 2021 12:50:14
	System	31 Mar 2021 12:50:14

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-03-31T08:50:07-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee136132-7646-496e-a11e-a9652a1f0c0e'	System	31 Mar 2021 12:50:14
User entered 'No (N)'	System	31 Mar 2021 12:50:14

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-03-31T08:50:10-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'ee136132-7646-496e-a11e-a9652a1f0c0e' User entered '31 Mar 2021 08:50:10'	System	31 Mar 2021 12:50:14
	System	31 Mar 2021 12:50:14

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-07T08:34:16-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9ce91950-7aad-4837-b4a5-360704c7ebd3' User entered 'No (N)'	System	07 Apr 2021 12:34:25
	System	07 Apr 2021 12:34:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-07T08:34:19-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9ce91950-7aad-4837-b4a5-360704c7ebd3' User entered 'No (N)'	System	07 Apr 2021 12:34:25
	System	07 Apr 2021 12:34:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEED)', Time: '2021-04-07T08:34:21-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '9ce91950-7aad-4837-b4a5-360704c7ebd3'	System	07 Apr 2021 12:34:25
User entered '07 Apr 2021 08:34:21'	System	07 Apr 2021 12:34:25

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-14T08:21:16-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '776d54a0-e8e2-4780-825b-28f37bada2b8' User entered 'No (N)'	System	14 Apr 2021 12:21:22
	System	14 Apr 2021 12:21:22

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-14T08:21:18-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '776d54a0-e8e2-4780-825b-28f37bada2b8' User entered 'No (N)'	System	14 Apr 2021 12:21:22
	System	14 Apr 2021 12:21:22

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEED)', Time: '2021-04-14T08:21:20-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '776d54a0-e8e2-4780-825b-28f37bada2b8' User entered '14 Apr 2021 08:21:20'	System	14 Apr 2021 12:21:22
	System	14 Apr 2021 12:21:22

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-21T18:20:07-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd9a4e77a-2048-42e6-aa7c-911f61f33de3' User entered 'No (N)'	System	21 Apr 2021 22:20:15
	System	21 Apr 2021 22:20:15

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-21T18:20:09-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd9a4e77a-2048-42e6-aa7c-911f61f33de3' User entered 'No (N)'	System	21 Apr 2021 22:20:15
	System	21 Apr 2021 22:20:15

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-21T18:20:12-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'd9a4e77a-2048-42e6-aa7c-911f61f33de3'	System	21 Apr 2021 22:20:15
User entered '21 Apr 2021 18:20:12'	System	21 Apr 2021 22:20:15

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-28T08:34:59-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2c98186b-5f86-4b0c-b557-1288bf0f3b7d' User entered 'No (N)'	System	28 Apr 2021 23:43:51
	System	28 Apr 2021 23:43:51

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-28T08:35:00-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2c98186b-5f86-4b0c-b557-1288bf0f3b7d' User entered 'No (N)'	System	28 Apr 2021 23:43:51
	System	28 Apr 2021 23:43:51

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3E160E6F-6C34-4223-AEBF-671C53C8FEBD)', Time: '2021-04-28T08:35:02-04:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: '2c98186b-5f86-4b0c-b557-1288bf0f3b7d' User entered '28 Apr 2021 08:35:02'	System	28 Apr 2021 23:43:51
	System	28 Apr 2021 23:43:51

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:59:01

US3832250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:59:01
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:59:01

US3832250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:31:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:49:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-01T08:30:33-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c6c47e4f-3219-4b8f-b117-9c392788b655'	System	01 Mar 2021 13:30:39
User entered 'No (N)'	System	01 Mar 2021 13:30:39

US3832250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:31:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:49:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AAB41B-73C0-4D66-9B11-5126E2C64648)', Time: '2021-03-01T08:30:36-05:00', User OID: 'PatientReportedOutcome (US3832250)', ODM File OID: 'c6c47e4f-3219-4b8f-b117-9c392788b655'	System	01 Mar 2021 13:30:39
User entered '01 Mar 2021 13:30:36'	System	01 Mar 2021 13:30:39

US3832250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:52:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Nov 2020 15:22:39

US3832250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:52:26
User entered '16 Nov 2020'	Alyssa-Kay Peay (b) (4)	16 Nov 2020 15:22:39

US3832250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:52:26
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	16 Nov 2020 15:22:39

US3832250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:52:26
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Nov 2020 15:22:39

US3832250

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:52:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Nov 2020 15:22:44

US3832250

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:33:37
User entered 'I'	System	16 Nov 2020 15:22:44

US3832250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:02:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Dec 2020 01:56:07

US3832250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:02:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
User closed query 'per source, 21 Dec 2020. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 21:57:32
Query 'per source, 21 Dec 2020. please confirm and update.' answered with 'Verified and updated.' (Site from CRA).	Rodolfo Barrera (b) (4)	25 Jan 2021 21:56:56
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 21:56:43
User opened query 'per source, 21 Dec 2020. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 14:53:42
User entered '18 Dec 2020'	Danyel Johnson (b) (4)	19 Dec 2020 01:56:07

US3832250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:02:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	19 Dec 2020 01:56:07

US3832250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:02:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
User entered empty.	Danyel Johnson (b) (4)	19 Dec 2020 01:56:07

US3832250

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:53:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Dec 2020 01:56:13

US3832250

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User entered 'I'	System	19 Dec 2020 01:56:13

US3832250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:54:27
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	19 Jan 2021 17:45:29

US3832250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:54:27
User entered '19 Jan 2021'	Rodolfo Barrera (b) (4)	19 Jan 2021 17:45:29

US3832250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:54:27
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	19 Jan 2021 17:45:29

US3832250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 14:54:27
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	19 Jan 2021 17:45:29

US3832250

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 14:54:38
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	19 Jan 2021 17:45:34

US3832250

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User entered '1'	System	19 Jan 2021 17:45:34

US3832250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:59
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Feb 2021 15:28:41

US3832250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:59
User entered '16 Feb 2021'	Rodolfo Barrera (b) (4)	16 Feb 2021 15:28:41

US3832250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:59
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	16 Feb 2021 15:28:41

US3832250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:59
User entered empty.	Rodolfo Barrera (b) (4)	16 Feb 2021 15:28:41

US3832250

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:40:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:07
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Feb 2021 15:28:45

US3832250

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:48:10
User entered '1'	System	16 Feb 2021 15:28:45

US3832250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:03
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered '30 Mar 2021'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:03
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:03
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	21 Apr 2021 20:56:03

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'No (N)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:56:11

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:56:11

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:56:11

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:56:11

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:11
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:56:11

US3832250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'No (N)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:16
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:16
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:52
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered '30 Mar 2021'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:52
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered '08:49'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:52
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 08:49'	System	21 Apr 2021 20:56:52

US3832250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	21 Apr 2021 20:56:57
	(b) (4)	

US3832250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:56:57

US3832250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	22 Apr 2021 19:50:34
	(b) (4)	

US3832250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered '22 Apr 2021'	Rodolfo Barrera (b) (4)	22 Apr 2021 19:50:34
	(b) (4)	

US3832250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	22 Apr 2021 19:50:34

US3832250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	22 Apr 2021 19:50:34
	(b) (4)	

US3832250

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:39
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	22 Apr 2021 19:50:49
	(b) (4)	

US3832250

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 19:50:49

US3832250

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:15
User entered 'Yes (Y)'	Emma Partin (b) (4)	21 Jan 2021 15:14:19

US3832250

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:15
User entered '21 Jan 2021'	Emma Partin (b) (4)	21 Jan 2021 15:14:19

US3832250

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[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 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:15
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	21 Jan 2021 15:14:19

US3832250

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

Form: Visit Date

Generated On: 12 Aug 2021 13:31:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 15:14:19

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered '21 Jan 2021'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:32:52
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:18:28
User entered '0'	(b) (4) Danyel Johnson (b) (4)	08 Apr 2021 12:57:47
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:50:17

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered 'Yes (Y)'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User closed query 'Per CDM, per Sponsor Review: 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)	16 Apr 2021 01:31:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:32:55
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:18:28
Query 'Per CDM, per Sponsor Review: 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).	Danyel Johnson (b) (4)	08 Apr 2021 12:57:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	Danyel Johnson (b) (4)	08 Apr 2021 12:57:47
User opened query 'Per CDM, per Sponsor Review: 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)	08 Apr 2021 11:39:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:50:17

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered '21 Jan 2021'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered 'Not Administered (NA)'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:41
User entered 'No (N)'	Emma Partin (b) (4)	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered empty.	System	21 Jan 2021 15:15:02

US3832250

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

Form: Unblinding

Generated On: 12 Aug 2021 13:31:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered empty.	System	21 Jan 2021 15:15:02

US3832250

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 21JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	26 Feb 2021 11:00:02 21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:52
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 21JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with '1F605220441' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 21:06:09
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 21JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Emma Partin (b) (4)	05 Feb 2021 19:45:16 21 Jan 2021 15:14:37

US3832250

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:52
User entered '21 Jan 2021'	Emma Partin (b) (4)	21 Jan 2021 15:14:37

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:49:52
User entered '10:02'	Emma Partin (b) (4)	21 Jan 2021 15:14:37

US3832250

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '21 Jan 2021 10:02'	System	21 Jan 2021 15:14:37

US3832250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:30
User entered 'Yes (Y)'	Emma Partin (b) (4)	21 Jan 2021 15:14:47

US3832250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:30
User entered '21 Jan 2021'	Emma Partin (b) (4)	21 Jan 2021 15:14:47

US3832250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:30
User entered '10:00'	Emma Partin (b) (4)	21 Jan 2021 15:14:47

US3832250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:17:39
User entered '21 Jan 2021 10:00'	System	21 Jan 2021 15:14:47

US3832250

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:31:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:59:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (DAY 8 on 31AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 07:56:44
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (DAY 8 on 31AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'UPDATED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 18:28:53
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (DAY 8 on 31AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 10:20:02
User closed query 'per source, no concomitant procedures. please enter EDC page.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:32:41
Query 'per source, no concomitant procedures. please enter EDC page.' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:29:59
User opened query 'per source, no concomitant procedures. please enter EDC page.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 18:31:21
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:05
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:32

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 15:34:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 15:34:01
Data point term sent to Coder	System	14 Apr 2021 15:33:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 14:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 14:23:41
Data point term sent to Coder	System	20 Oct 2020 14:23:14
User entered 'NAUSEA'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 18:16:24
	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 18:16:24
	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'No (N)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '2 Oct 2020'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered empty.	System	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:23:03
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	20 Oct 2020 14:23:03
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 14:23:03
User entered '20 Oct 2020' reason for change: Data Entry Error	Emma Partin (b) (4)	20 Oct 2020 14:23:03
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 14:22:46
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered empty.	System	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'No (N)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'Not Related (NOT RELATED)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered 'Not Related (NOT RELATED)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	25 Nov 2020 18:16:24
User entered 'None (NONE)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'I'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '0'	Emma Partin (b) (4)	20 Oct 2020 14:22:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'STARTED PHENEGAN'	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered empty.	Emma Partin (b) (4)	20 Oct 2020 14:22:46
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered '0'	System	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered '1'	System	20 Oct 2020 14:22:46

US3832250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:31:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 15:34:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 15:34:01
Data point term sent to Coder	System	14 Apr 2021 15:33:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Feb 2021 18:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 18:28:50
Data point term sent to Coder	System	10 Feb 2021 18:28:28
User entered 'Headache'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'No (N)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:51:17
Query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate. ' answered with 'Data is correct as reported as per Sub-I/PI review' (Site from DM).	Danyel Johnson (b) (4)	26 Apr 2021 19:02:18
User opened query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:24:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:18:28
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:56:51
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' answered with 'updated per review' (Site from DM).	Danyel Johnson (b) (4)	25 Mar 2021 12:09:13
Signature has been broken.	Danyel Johnson (b) (4)	25 Mar 2021 12:08:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	25 Mar 2021 12:08:56

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 02:42:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	10 Feb 2021 18:28:11
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'No (N)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User closed query 'Per source - 31Au2020, please reconcile' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:35:05
Query 'Per source - 31Au2020, please reconcile' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:34:21
Signature has been broken.	Emma Partin (b) (4)	14 Apr 2021 14:02:47
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per source - 31Au2020, please reconcile' (Site from CRA).	Emma Partin (b) (4)	14 Apr 2021 14:02:30
User signature succeeded.	(b) (4)	
User closed query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Headache was initially noted on 30 Aug 2020. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	Emma Partin (b) (4)	14 Apr 2021 14:02:30
Query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Headache was initially noted on 30 Aug 2020. Please review and update accordingly. Otherwise, clarify.' answered with 'updated per review' (Site from DM).	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 15:06:56
User entered '30 Aug 2020' reason for change: Data Entry Error	Gowdhami Mohan (b) (4)	12 Apr 2021 23:18:28
User opened query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Headache was initially noted on 30 Aug 2020. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 13:56:53
Query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Headache was initially noted on 30 Aug 2020. Please review and update accordingly. Otherwise, clarify.' answered with 'updated per review' (Site from DM).	Danyel Johnson (b) (4)	25 Mar 2021 12:09:23
Signature has been broken.	(b) (4)	
User entered '30 Aug 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	25 Mar 2021 12:08:56
User opened query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Headache was initially noted on 30 Aug 2020. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	25 Mar 2021 12:08:56
	(b) (4), (b) (6)	14 Mar 2021 02:42:14
	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered empty.	System	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'No (N)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered empty.	System	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'No (N)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11
	(b) (4)	

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User signature succeeded.	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	10 Feb 2021 18:28:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 18:28:24
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:24
	(b) (4)	
	System	10 Feb 2021 18:28:11
	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'I'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '0'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:14:22
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:35:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	Danyel Johnson (b) (4)	10 Feb 2021 18:28:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered '0'	System	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16
User entered '0'	System	10 Feb 2021 18:28:11

US3832250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	14 Apr 2021 15:32:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Apr 2021 15:32:16

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:31:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:59:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User closed query 'Per DM CLR: Per Diary Dose 1 Day 7 (30AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:26:24
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3 (26AUG2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:26:22
Query 'Per DM CLR: Per Diary Dose 1 Day 7 (30AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Per progress note collected at day 8 subject denies any changes in medications' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Feb 2021 18:23:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 3 (26AUG2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.'	Danyel Johnson (b) (4)	10 Feb 2021 18:23:46
answered with 'Per progress note collected at day 8 subject denies any changes in medications' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 1 Day 7 (30AUG2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:19:05
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3 (26AUG2020), Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:19:01
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:30
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:53:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:55:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 10:55:44
Data point term sent to Coder	System	25 Aug 2020 10:55:03
User entered 'Nuvaring'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:08:07
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Verified and updated.' (Site from DM).	Rodolfo Barrera (b) (4) (b) (4)	05 Feb 2021 15:57:29
DataPoint Un-verified.	Rodolfo Barrera (b) (4) (b) (4)	05 Feb 2021 15:57:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Rodolfo Barrera (b) (4) (b) (4)	05 Feb 2021 15:57:14
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 20:18:36
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Contraception'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'l'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'device'	Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User closed query 'Per CDM: Per page 37 of CCGs, Select the Frequency from the drop-down list provided. If frequency is not listed, select 'Other' and specify in the text box provided. However the Frequency is indicated as Other 'Monthly', this can be one of the available option 'every month' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:30:49
Query 'Per CDM: Per page 37 of CCGs, Select the Frequency from the drop-down list provided. If frequency is not listed, select 'Other' and specify in the text box provided. However the Frequency is indicated as Other 'Monthly', this can be one of the available option 'every month' from the drop down list. Please update accordingly. Else Clarify.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 14:57:25
User entered 'every month (QM)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 14:56:45
User opened query 'Per CDM: Per page 37 of CCGs, Select the Frequency from the drop-down list provided. If frequency is not listed, select 'Other' and specify in the text box provided. However the Frequency is indicated as Other 'Monthly', this can be one of the available option 'every month' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:47:56
User entered 'other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Oct 2020 14:56:45
User entered 'monthly'	(b) (4) Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:54:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'intrauterine'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered '0'	Alyssa-Kay Peay (b) (4)	25 Aug 2020 10:54:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:36:13
User closed query 'per source, no. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:36:05
Query 'per source, no. please confirm and update.' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:32:26
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:32:04
User opened query 'per source, no. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 18:13:32
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:13:14
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:36:10
User closed query 'per source, 21 Sep 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:36:08
Query 'per source, 21 Sep 2020. please confirm and update' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:32:35
User entered '21 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:32:16
User entered 'un Aug 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:32:04
User opened query 'per source, 21 Sep 2020. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 18:14:01
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:13:15
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User entered '1'	System	15 Oct 2020 14:56:45
User entered empty.	System	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User entered '1'	System	15 Oct 2020 14:56:45
User entered empty.	System	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:10:05
User entered '802 (802)'	System	15 Oct 2020 14:56:45
User entered empty.	System	25 Aug 2020 10:54:05

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 05:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 05:02:44
Data point term sent to Coder	System	20 Oct 2020 14:22:09
User entered 'PHENEGAN'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'No (N)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'AE- NAUSEA'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered '25'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'mg (mg)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty.	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'once daily (QD)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty.	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Oral (ORAL)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty.	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered '2 Oct 2020'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered '0'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 13:36:27
User closed query 'Please confirm subject is taking med as the AE has ended.' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 13:36:24
Query 'Please confirm subject is taking med as the AE has ended.' answered with 'Ongoing on a PRN basis per subject report' (Site from CRA).	Danyel Johnson (b) (4)	16 Dec 2020 01:33:37
User opened query 'Please confirm subject is taking med as the AE has ended.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:15:08
	(b) (4), (b) (6)	25 Nov 2020 18:14:49
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'Yes (Y)'	Emma Partin (b) (4)	20 Oct 2020 14:21:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered empty.	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

US3832250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:12:40
User entered 'No (N)'	Emma Partin (b) (4) (b) (4)	20 Oct 2020 14:21:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 14:21:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 14:21:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 14:21:09

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:31:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:32:50
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	16 Dec 2020 01:30:12

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:43

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:08:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 10:45:05

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:43

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:08:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered 'Pregnancy (PREGNANCY)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 10:45:05

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:15:27
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:08:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:39:53
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 10:45:05