

US3812197 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3812197

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 20:04:54

Generated On: 12 Aug 2021 13:34:50

[Participant ID](#)

US3812197

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

US3812197

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Date of Birth (MMM yyyy)	(b) (6) 1982
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 20:04:57

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 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) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 20:04:57

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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) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:32 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:32
Height (<i>xxx.x</i>)	68.7 in
Weight (<i>xxx.x</i>)	184.6 lb
BMI (<i>xxx.x</i>)	27.55676 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 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: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 20:04:58

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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) 20 Feb 2021 20:04:58

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 104973

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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)	17 AUG 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:32
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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)	17 AUG 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:46
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 12:16 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 12:16

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

12:05 (24 HR)

Collection date and time (derived)

17 AUG 2020 12:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:08	17 AUG 2020 12:08
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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 13:34:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:53

PC Open Date & Time

17 AUG 2020 12:36

PC Close Date & Time

17 AUG 2020 15:06

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	18 AUG 2020 01:53
PC Open Date & Time	17 AUG 2020 16:01
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

18 AUG 2020 15:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 17:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

21 AUG 2020 00:08

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 06:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:54

PC Open Date & Time

17 AUG 2020 12:36

PC Close Date & Time

17 AUG 2020 15:06

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

17 AUG 2020 16:52

PC Open Date & Time

17 AUG 2020 16:01

PC Close Date & Time

18 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

19 AUG 2020 12:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

21 AUG 2020 00:09

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

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

22 AUG 2020 06:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

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

23 AUG 2020 13:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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 ☐

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 12:54
PC Open Date & Time	17 AUG 2020 12:36
PC Close Date & Time	17 AUG 2020 15:06

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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 ☐

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 16:52
PC Open Date & Time	17 AUG 2020 16:01
PC Close Date & Time	18 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:05
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:06
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 00:09
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 4563

EAB) (1725)

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 06:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

53 of 4563

EAB) (1725)

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:34
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT
NO SAFETY CALL NEEDED

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT ,
NO SAFETY CALL MADE

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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	

US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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.

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

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?

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT ,
NO SAFETY CALL MADE

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT ,
NO SAFETY CALL MADE

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT ,
NO SAFETY CALL MADE

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:05:05

Generated On: 12 Aug 2021 13:34:50

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 20:05:05

Generated On: 12 Aug 2021 13:34:50

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) _____

US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:05:05

Generated On: 12 Aug 2021 13:34:50

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.

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3812197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:58

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 OCT 2020 11:14:14
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 00:01:24

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 11:53:42

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 ☒

Yes ☐

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

19 NOV 2020 12:35:51

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

28 NOV 2020 13:08:56

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 00:03:27
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

11 DEC 2020 13:23:14

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 00:05:45
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

23 DEC 2020 19:24:09

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 09:28:36

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

06 JAN 2021 00:04:43

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

13 JAN 2021 09:10:13

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 00:01:30

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 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	28 JAN 2021 09:03:25
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

06 FEB 2021 17:59:54

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 09:26:29
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 11:51:25

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

26 FEB 2021 16:11:08

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 09:31:27

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

13 MAR 2021 10:23:21

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

20 MAR 2021 10:25:53

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

24 MAR 2021 01:49:49

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

03 APR 2021 11:40:39

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 01:42:28
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

17 APR 2021 17:23:37

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

21 APR 2021 08:14:37

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Date and time of submission

28 APR 2021 08:46:41

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 MAY 2021 00:01

Patient Cloud Close Date & Time

09 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAY 2021 00:01

Patient Cloud Close Date & Time

16 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

02 JUN 2021 00:01

Patient Cloud Close Date & Time

06 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

09 JUN 2021 00:01

Patient Cloud Close Date & Time

13 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

27 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

04 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JUL 2021 00:01

Patient Cloud Close Date & Time

11 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

14 JUL 2021 00:01

Patient Cloud Close Date & Time

18 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 AUG 2021 00:01

Patient Cloud Close Date & Time

08 AUG 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

15 AUG 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 SEP 2021 00:01

Patient Cloud Close Date & Time

05 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 SEP 2021 00:01

Patient Cloud Close Date & Time

12 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 SEP 2021 00:01

Patient Cloud Close Date & Time

19 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 SEP 2021 00:01

Patient Cloud Close Date & Time

26 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

10 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2021 00:01

Patient Cloud Close Date & Time

17 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2021 00:01

Patient Cloud Close Date & Time

31 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

07 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2021 00:01

Patient Cloud Close Date & Time

14 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2021 00:01

Patient Cloud Close Date & Time

21 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

28 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 DEC 2021 00:01

Patient Cloud Close Date & Time

05 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 DEC 2021 00:01

Patient Cloud Close Date & Time

12 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 DEC 2021 00:01

Patient Cloud Close Date & Time

19 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 DEC 2021 00:01

Patient Cloud Close Date & Time

26 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

02 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 JAN 2022 00:01

Patient Cloud Close Date & Time

09 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 JAN 2022 00:01

Patient Cloud Close Date & Time

16 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

23 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

30 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

02 FEB 2022 00:01

Patient Cloud Close Date & Time

06 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

09 FEB 2022 00:01

Patient Cloud Close Date & Time

13 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

27 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

02 MAR 2022 00:01

Patient Cloud Close Date & Time

06 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

09 MAR 2022 00:01

Patient Cloud Close Date & Time

13 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

20 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

10 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 APR 2022 00:01

Patient Cloud Close Date & Time

17 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

24 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

01 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 MAY 2022 00:01

Patient Cloud Close Date & Time

08 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

22 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 JUN 2022 00:01

Patient Cloud Close Date & Time

05 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 JUN 2022 00:01

Patient Cloud Close Date & Time

12 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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°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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 JUN 2022 00:01

Patient Cloud Close Date & Time

19 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 JUN 2022 00:01

Patient Cloud Close Date & Time

26 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

03 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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 <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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 JUL 2022 00:01

Patient Cloud Close Date & Time

17 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

24 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 AUG 2022 00:01

Patient Cloud Close Date & Time

14 AUG 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 AUG 2022 00:01

Patient Cloud Close Date & Time

21 AUG 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 SEP 2022 00:01

Patient Cloud Close Date & Time

11 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

14 SEP 2022 00:01

Patient Cloud Close Date & Time

18 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

25 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2022 00:01

Patient Cloud Close Date & Time

09 OCT 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 OCT 2022 00:01

Patient Cloud Close Date & Time

16 OCT 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Patient Cloud Close Date & Time

23 OCT 2022 23:59

US3812197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:34:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 09:31:45

US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

SUBJECT IN CONVALESCENT ,
NO SAFETY CALL MADE

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	16:13 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 16:13
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

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.

US3812197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

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

Collection date (dd MMM yyyy)	25 MAR 2021
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Collection time (00:00-23:59)	16:25 (24 HR)
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Collection date and time (derived)	25 MAR 2021 16:25
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US3812197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:29:05

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:29:05

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Date of Contact	27 AUG 2020
Time of Contact	17:20
Date and Time of Contact (derived)	27 AUG 2020 17:20
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	96.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (10)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (11)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 SEP 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 21 Apr 2021 14:42:32

Generated On: 12 Aug 2021 13:34:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Date of Visit 27 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 27 AUG 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation?

Yes ☐
No ☐

Start Date

End Date

ECMO?

Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires
Vasopressors

Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐
No ☒

Start Date

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 AUG 2020
Day 5	Yes	31 AUG 2020
Day 7	Yes	2 SEP 2020
Day 9	Yes	4 SEP 2020
Day 14	Yes	09 SEP 2020
Day 21	Yes	16 SEP 2020
Day 28	Yes	29 SEP 2020

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	SICKD1

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:29 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:29
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3812197

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 AUG 2020

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	SICKD28

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:05
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 SEP 2020

US3812197

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3812197

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3812197

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Height	68.7 in
Weight	192.8 lb
BMI (xxx.x)	28.78084

US3812197

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Height	68.7 in
Weight	192.8 lb
BMI (xxx.x)	28.78084
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)	28 JAN 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 09:10
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812197

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Height	68.7 in
Weight	192.8 lb
BMI (xxx.x)	28.78084
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)	28 JAN 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 10:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3812197

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

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 20:04:57

Generated On: 12 Aug 2021 13:34:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3812197

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

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 09:44

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

What was the frequency of the study treatment dosing? ONCE

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

US3812197

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

28 JAN 2021 09:20

US3812197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

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

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00 - 23:59)	09:25
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Collection Date and Time (derived)	28 JAN 2021 09:25
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US3812197

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

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 FEB 2021

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

Comments LEFT MESSAGE TO CALL BACK

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

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

US3812197

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

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

Visit date (dd MMM yyyy)	26 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

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)	26 FEB 2021
Time of assessment (00:00-23:59)	15:51 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:51
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:33
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3812197

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

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.

US3812197

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 16:02 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 16:02

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

US3812197

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812197

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:53:44

Generated On: 12 Aug 2021 13:34:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	16:13 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 16:13
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812197

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

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.

US3812197

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 16:25 (24 HR)

Collection date and time (derived) 25 MAR 2021 16:25

US3812197

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 18:29:42

Generated On: 12 Aug 2021 13:34:50

AEID	USA-US111-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	24 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)	28 AUG 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"/>

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EAB) (1725)

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US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 18:29:42

Generated On: 12 Aug 2021 13:34:50

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 18:29:42

Generated On: 12 Aug 2021 13:34:50

SUBJECT HAD A NEGATIVE PCR SWAB AT HIS DAY 1 VISIT ON 17 AUG 2020. SUBJECT REPORTED COVID-19 RELATED SYMPTOMS THAT STARTED ON AUG 24TH. THE SUBJECT EXPERIENCED THE FOLLOWING SYMPTOMS AFTER RETURNING FROM HIS RECENT VEGAS TRIP: COUGH, FATIGUE, MYALGIA, HEADACHE, NASAL CONGESTION, AND RUNNY NOSE. THE SUBJECT DENIES USING ANY MEDICATIONS OR UNDERGOING ANY MEDICAL TREATMENT FOR HIS SYMPTOMS. THE SUBJECT RETURNED TO THE CLINIC FOR AN ILLNESS VISIT ON 27 AUG 2020. THE SUBJECT HAD A POSITIVE PCR SWAB AT HIS DAY 1 ILLNESS VISIT. CURRENTLY THE SUBJECT IS ASYMPTOMATIC.

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)	

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 18:29:05

Generated On: 12 Aug 2021 13:34:50

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

Yes ☒

No ☐

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

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:29:04

Generated On: 12 Aug 2021 13:34:50

Name of Medication DEPOMEDROL

Prophylaxis Yes ☒
No ☐

Indication SEASONAL ALLERGIES

Dose per administration 2

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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US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:29:04

Generated On: 12 Aug 2021 13:34:50

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3812197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 20:04:55

Generated On: 12 Aug 2021 13:34:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

End of Study / Study Discontinuation	False
All	False

Date of missed or out of window visit or assessment	21 SEP 2020
---	-------------

Category

Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	SUBJECT WAS IN CONVALESCENT PERIOD. VISIT 2 NOT DONE.

Description of Relationship to COVID-19

Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	22 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	29 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	6 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input checked="" type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	True
Vital Signs - Dosing	False
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	True
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	20 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	True
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812197

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

Date of dosing discontinuation (dd MMM yyyy) 17 AUG 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 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 checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 20 Feb 2021 20:04:56

Generated On: 12 Aug 2021 13:34:50

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 ☐

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/SEP/2020 14:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	10/SEP/2020 10:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/SEP/2020 12:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/SEP/2020 09:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/OCT/2020 20:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/OCT/2020 17:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 08 Apr 2021 01:38:43

Generated On: 12 Aug 2021 13:34:50

SAEID	USA-US111-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/APR/2021 16:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812197 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812197

Form: Participant Creation

Generated On: 12 Aug 2021 13:34:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'US3812197'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 16:59:48

US3812197

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:05

US3812197

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:46
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 16:59:49

US3812197

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:01:46
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	17 Aug 2020 17:33:05

US3812197

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'SCRN'	System	17 Aug 2020 17:33:05

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered (b) (6) 1982'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 16:59:50

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '38'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'YEARS'	System	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '38'	System	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered 'Male (M)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:01:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:46

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered '17 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Aug 2020'	System	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2020'	System	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered 'Amendment 2 (2)'	Breanna Galibert (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:16

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:00
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 16:59:49

US3812197

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'I'	System	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:02:05
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:34:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:02:07
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Aug 2020 18:21:01

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Finger repair operation, LLT: Finger repair operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:42:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:42:52
Data point term sent to Coder	System	27 Aug 2020 18:21:53
User entered 'RIGHT RING FINGER REPAIR'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:21:18

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Fractured finger - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:50:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:50:45
Data point term sent to Coder	System	27 Aug 2020 18:21:54
User entered 'RIGHT BROKEN RING FINGER'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:21:36

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:23
Data point term sent to Coder	System	27 Aug 2020 18:21:57
User entered 'SEASONAL ALLERGIES'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 1998'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 1998'	System	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '1998'	System	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered empty.	System	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered empty.	System	27 Aug 2020 18:21:50

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:28
Data point term sent to Coder	System	27 Aug 2020 18:22:59
User entered 'HIATAL HERNIA'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'Jan 2000'	System	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '2000'	System	27 Aug 2020 18:22:26

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered '17 Aug 2020'	Breanna Galibert (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered '11:32'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered '17 Aug 2020 11:32'	System	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered '68.7' in	Breanna Galibert (b) (4)	27 Aug 2020 18:20:47
DataPoint set to visible.	(b) (4) System	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered '184.6' lb	Breanna Galibert (b) (4)	27 Aug 2020 18:20:47
DataPoint set to visible.	(b) (4) System	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
Amendment Manager: User entered '27.55676'	System	17 Sep 2020 00:00:11
User entered '27.6'	System	27 Aug 2020 18:20:47
DataPoint set to visible.	System	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'kg/m2'	System	27 Aug 2020 18:20:47
DataPoint set to visible.	System	17 Aug 2020 17:33:30

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered 'Other (Other)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'bpm'	System	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'breaths/min'	System	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'mmHg'	System	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:15
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User entered 'mmHg'	System	27 Aug 2020 18:20:47

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44

US3812197

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:47:32
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	05 Sep 2020 21:38:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Aug 2020 18:17:52

US3812197

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '17 Aug 2020' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 23:47:32
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 21:38:51
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4) (b) (4)	05 Sep 2020 21:38:51
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:29:25
User entered '17 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:17:52

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered empty.	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '0'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '0'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:39:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:55
User entered empty.	Breanna Galibert (b) (4)	27 Aug 2020 18:18:09

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:05:09
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Aug 2020 17:33:39

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:05:09
User entered '17 Aug 2020'	Breanna Galibert (b) (4)	17 Aug 2020 17:33:39

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:09
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:33:39

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'VISIT1'	System	17 Aug 2020 17:33:39

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:00:17

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:03:12
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:03:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 17:00:17
User entered '104973' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:00:17

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:00:17

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:44

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:44

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:44

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:44

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Aug 2020 18:18:44

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:05:27
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	21 Sep 2020 18:34:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:40:24

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '17 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '11:32'	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered '17 Aug 2020 11:32'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '97.4' F	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered empty.	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '59'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'bpm'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '13'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'breaths/min'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '108'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'mmHg'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '60'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'mmHg'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '17 Aug 2020'	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '12:46'	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered '17 Aug 2020 12:46'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '97.8' F	Breanna Galibert (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '60'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'bpm'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '14'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'breaths/min'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '104'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'mmHg'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:16
User entered '62'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'mmHg'	System	27 Aug 2020 18:20:22

US3812197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:21
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:15

US3812197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:21
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:15

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered empty.	Breanna Galibert (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered '17 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered '12:16'	Breanna Galibert (b) (4) (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered '17 Aug 2020 12:16'	System	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:06:37
User entered 'ONCE'	System	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 17:34:22

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:50
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:56

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:50
User entered '17 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:56

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:50
User entered '12:05'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:18:56

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered '17 Aug 2020 12:05'	System	27 Aug 2020 18:18:56

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:56
User entered '17 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:56
User entered '12:08'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered '17 Aug 2020 12:08'	System	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	27 Aug 2020 18:19:07

US3812197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:30:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:19:12

US3812197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	27 Aug 2020 18:19:12

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3'	System	17 Aug 2020 17:53:33
User entered 'Yes (Y)'	System	17 Aug 2020 17:53:33

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3'	System	17 Aug 2020 17:53:33
User entered '97.8'	System	17 Aug 2020 17:53:33

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:26', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3'	System	17 Aug 2020 17:53:33
User entered 'No (N)'	System	17 Aug 2020 17:53:33

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:31', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3'	System	17 Aug 2020 17:53:33
User entered '17 Aug 2020 12:53'	System	17 Aug 2020 17:53:33

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 12:36'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:52:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaa'	System	18 Aug 2020 06:53:07
User entered 'Yes (Y)'	System	18 Aug 2020 06:53:07

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:52:59', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaa'	System	18 Aug 2020 06:53:07
User entered '97.8'	System	18 Aug 2020 06:53:07

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:53:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaa'	System	18 Aug 2020 06:53:07
User entered 'No (N)'	System	18 Aug 2020 06:53:07

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:53:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaaad'	System	18 Aug 2020 06:53:07
User entered '18 Aug 2020 01:53'	System	18 Aug 2020 06:53:07

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 16:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 2'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca'	System	18 Aug 2020 20:21:19
User entered 'Yes (Y)'	System	18 Aug 2020 20:21:19

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca'	System	18 Aug 2020 20:21:19
User entered '97.2'	System	18 Aug 2020 20:21:19

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca'	System	18 Aug 2020 20:21:19
User entered 'No (N)'	System	18 Aug 2020 20:21:19

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca'	System	18 Aug 2020 20:21:19
User entered '18 Aug 2020 15:21'	System	18 Aug 2020 20:21:19

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 3'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2'	System	19 Aug 2020 22:16:11
User entered 'Yes (Y)'	System	19 Aug 2020 22:16:11

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2'	System	19 Aug 2020 22:16:11
User entered '97.3'	System	19 Aug 2020 22:16:11

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2'	System	19 Aug 2020 22:16:11
User entered 'No (N)'	System	19 Aug 2020 22:16:11

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2'	System	19 Aug 2020 22:16:11
User entered '19 Aug 2020 17:16'	System	19 Aug 2020 22:16:11

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 4'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:49', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9'	System	21 Aug 2020 05:09:01
User entered 'Yes (Y)'	System	21 Aug 2020 05:09:01

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:53', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9' User entered '97.8'	System	21 Aug 2020 05:09:01
	System	21 Aug 2020 05:09:01

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:55', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9'	System	21 Aug 2020 05:09:01
User entered 'No (N)'	System	21 Aug 2020 05:09:01

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:57', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9'	System	21 Aug 2020 05:09:01
User entered '21 Aug 2020 00:08'	System	21 Aug 2020 05:09:01

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 5'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1'	System	22 Aug 2020 13:20:02
User entered 'Yes (Y)'	System	22 Aug 2020 13:20:02

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:52', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1'	System	22 Aug 2020 13:20:02
User entered '97.7'	System	22 Aug 2020 13:20:02

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1'	System	22 Aug 2020 13:20:02
User entered 'No (N)'	System	22 Aug 2020 13:20:02

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:56', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1'	System	22 Aug 2020 13:20:02
User entered '22 Aug 2020 06:19'	System	22 Aug 2020 13:20:02

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 6'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac'	System	23 Aug 2020 01:41:16
User entered 'Yes (Y)'	System	23 Aug 2020 01:41:16

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac'	System	23 Aug 2020 01:41:16
User entered '97.8'	System	23 Aug 2020 01:41:16

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac'	System	23 Aug 2020 01:41:16
User entered 'No (N)'	System	23 Aug 2020 01:41:16

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac'	System	23 Aug 2020 01:41:16
User entered '22 Aug 2020 18:41'	System	23 Aug 2020 01:41:16

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 7'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b'	System	23 Aug 2020 20:52:37
User entered 'Yes (Y)'	System	23 Aug 2020 20:52:37

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b'	System	23 Aug 2020 20:52:37
User entered '97.6'	System	23 Aug 2020 20:52:37

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b'	System	23 Aug 2020 20:52:37
User entered 'No (N)'	System	23 Aug 2020 20:52:37

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:35', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b'	System	23 Aug 2020 20:52:37
User entered '23 Aug 2020 13:52'	System	23 Aug 2020 20:52:37

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522'	System	17 Aug 2020 17:54:03
User entered 'None (1)'	System	17 Aug 2020 17:54:03

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522'	System	17 Aug 2020 17:54:03
User entered 'No (N)'	System	17 Aug 2020 17:54:03

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:50', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522'	System	17 Aug 2020 17:54:03
User entered 'No (N)'	System	17 Aug 2020 17:54:03

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:56', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522'	System	17 Aug 2020 17:54:03
User entered 'None (1)'	System	17 Aug 2020 17:54:03

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522'	System	17 Aug 2020 17:54:03
User entered '17 Aug 2020 12:54'	System	17 Aug 2020 17:54:03

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 12:36'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54'	System	17 Aug 2020 21:52:22
User entered 'None (1)'	System	17 Aug 2020 21:52:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54'	System	17 Aug 2020 21:52:22
User entered 'No (N)'	System	17 Aug 2020 21:52:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:15', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54'	System	17 Aug 2020 21:52:22
User entered 'No (N)'	System	17 Aug 2020 21:52:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:17', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54'	System	17 Aug 2020 21:52:22
User entered 'None (1)'	System	17 Aug 2020 21:52:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54'	System	17 Aug 2020 21:52:22
User entered '17 Aug 2020 16:52'	System	17 Aug 2020 21:52:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 16:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 2'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3'	System	18 Aug 2020 17:04:56
User entered 'None (1)'	System	18 Aug 2020 17:04:56

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3'	System	18 Aug 2020 17:04:56
User entered 'No (N)'	System	18 Aug 2020 17:04:56

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:49', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3'	System	18 Aug 2020 17:04:56
User entered 'No (N)'	System	18 Aug 2020 17:04:56

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3'	System	18 Aug 2020 17:04:56
User entered 'None (1)'	System	18 Aug 2020 17:04:56

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3'	System	18 Aug 2020 17:04:56
User entered '18 Aug 2020 12:04'	System	18 Aug 2020 17:04:56

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 3'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487'	System	19 Aug 2020 17:06:32
User entered 'None (1)'	System	19 Aug 2020 17:06:32

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487'	System	19 Aug 2020 17:06:32
User entered 'No (N)'	System	19 Aug 2020 17:06:32

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487'	System	19 Aug 2020 17:06:32
User entered 'No (N)'	System	19 Aug 2020 17:06:32

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487'	System	19 Aug 2020 17:06:32
User entered 'None (1)'	System	19 Aug 2020 17:06:32

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:29', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487'	System	19 Aug 2020 17:06:32
User entered '19 Aug 2020 12:06'	System	19 Aug 2020 17:06:32

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 4'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:01', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee'	System	21 Aug 2020 05:09:11
User entered 'None (1)'	System	21 Aug 2020 05:09:11

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee'	System	21 Aug 2020 05:09:11
User entered 'No (N)'	System	21 Aug 2020 05:09:11

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee'	System	21 Aug 2020 05:09:11
User entered 'No (N)'	System	21 Aug 2020 05:09:11

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee'	System	21 Aug 2020 05:09:11
User entered 'None (1)'	System	21 Aug 2020 05:09:11

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee'	System	21 Aug 2020 05:09:11
User entered '21 Aug 2020 00:09'	System	21 Aug 2020 05:09:11

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 5'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012'	System	22 Aug 2020 13:20:09
User entered 'None (1)'	System	22 Aug 2020 13:20:09

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012'	System	22 Aug 2020 13:20:09
User entered 'No (N)'	System	22 Aug 2020 13:20:09

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012'	System	22 Aug 2020 13:20:09
User entered 'No (N)'	System	22 Aug 2020 13:20:09

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012'	System	22 Aug 2020 13:20:09
User entered 'None (1)'	System	22 Aug 2020 13:20:09

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012'	System	22 Aug 2020 13:20:09
User entered '22 Aug 2020 06:20'	System	22 Aug 2020 13:20:09

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 6'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027'	System	23 Aug 2020 01:41:27
User entered 'None (1)'	System	23 Aug 2020 01:41:27

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027'	System	23 Aug 2020 01:41:27
User entered 'No (N)'	System	23 Aug 2020 01:41:27

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027'	System	23 Aug 2020 01:41:27
User entered 'No (N)'	System	23 Aug 2020 01:41:27

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:22', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027'	System	23 Aug 2020 01:41:27
User entered 'None (1)'	System	23 Aug 2020 01:41:27

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027'	System	23 Aug 2020 01:41:27
User entered '22 Aug 2020 18:41'	System	23 Aug 2020 01:41:27

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 7'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:32', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0'	System	23 Aug 2020 20:33:46
User entered 'None (1)'	System	23 Aug 2020 20:33:46

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0'	System	23 Aug 2020 20:33:46
User entered 'No (N)'	System	23 Aug 2020 20:33:46

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0'	System	23 Aug 2020 20:33:46
User entered 'No (N)'	System	23 Aug 2020 20:33:46

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0'	System	23 Aug 2020 20:33:46
User entered 'None (1)'	System	23 Aug 2020 20:33:46

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:44', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0'	System	23 Aug 2020 20:33:46
User entered '23 Aug 2020 13:33'	System	23 Aug 2020 20:33:46

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:15', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'None (0)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered 'No (N)'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e'	System	17 Aug 2020 17:54:22
User entered '17 Aug 2020 12:54'	System	17 Aug 2020 17:54:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 12:36'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:23', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:28', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'None (0)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:31', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered 'No (N)'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe'	System	17 Aug 2020 21:52:34
User entered '17 Aug 2020 16:52'	System	17 Aug 2020 21:52:34

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '17 Aug 2020 16:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 2'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:57', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:59', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'None (0)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered 'No (N)'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9'	System	18 Aug 2020 17:05:12
User entered '18 Aug 2020 12:05'	System	18 Aug 2020 17:05:12

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 3'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'None (0)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'None (0)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'None (0)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:37', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' User entered 'None (0)'	System	19 Aug 2020 17:06:48
	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:39', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'None (0)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'None (0)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:43', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered 'No (N)'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:46', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1'	System	19 Aug 2020 17:06:48
User entered '19 Aug 2020 12:06'	System	19 Aug 2020 17:06:48

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 4'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'None (0)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered 'No (N)'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375'	System	21 Aug 2020 05:09:27
User entered '21 Aug 2020 00:09'	System	21 Aug 2020 05:09:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 5'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:12', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:17', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'None (0)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:22', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered 'No (N)'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:26', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390'	System	22 Aug 2020 13:20:27
User entered '22 Aug 2020 06:20'	System	22 Aug 2020 13:20:27

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 6'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:29', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:32', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'None (0)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered 'No (N)'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376'	System	23 Aug 2020 01:41:41
User entered '22 Aug 2020 18:41'	System	23 Aug 2020 01:41:41

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 7'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:48', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:50', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:53', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:55', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'None (0)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:58', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered 'No (N)'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:34:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60'	System	23 Aug 2020 20:34:01
User entered '23 Aug 2020 13:34'	System	23 Aug 2020 20:34:01

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:34:22

US3812197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:31:07
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Aug 2020 18:22:42

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:53
DataPoint Verified.	System	16 Dec 2020 23:30:25
User entered '25 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:31:07
	Breanna Galibert (b) (4)	27 Aug 2020 18:22:42
	(b) (4)	

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:31:07
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:42

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:31:07
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:42

US3812197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:31:11
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:18:15

US3812197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	02 Sep 2020 20:18:15

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 08:11:35
Query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:15:14
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:15:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:17:58
User opened query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:17:49
User closed query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 22:24:56
Query 'Data is required. Please complete.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from System).	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:27:45
Query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:27:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 21:27:18
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:27:18
User opened query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:32:55
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:21:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 21:27:18
User entered '31 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:21:02

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 21:27:18
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	02 Sep 2020 20:21:02

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT NO SAFETY CALL NEEDED' reason for change: Per Query Resolution	Angie Kean (b) (4)	29 Oct 2020 19:15:09
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:21:02

US3812197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:33:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:33:09
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:21:07

US3812197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	02 Sep 2020 20:21:07

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 08:11:41
Query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:14:45
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:14:40
User opened query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:29:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:21:37
User closed query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 22:25:09
Query 'Data is required. Please complete.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from System).	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:29:03
Query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 21:28:45
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 21:28:45
User opened query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:34:08
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 02:42:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 02:42:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Sep 2020 02:42:01
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 21:56:10
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	06 Sep 2020 21:56:10
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 21:56:10
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	06 Sep 2020 21:56:04
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 21:55:33

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 21:28:45
User entered '7 Sep 2020' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Sep 2020 02:42:01
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Sep 2020 21:56:04
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	06 Sep 2020 21:56:04
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	06 Sep 2020 21:56:04
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Sep 2020 21:55:33
User entered '31 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 21:55:33

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 21:28:45
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Sep 2020 02:42:01
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	06 Sep 2020 21:56:04
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	06 Sep 2020 21:55:33

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change: Per Query Resolution	(b) (4) Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:14:40
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 21:55:33

US3812197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Sep 2020 12:57:00

US3812197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	13 Sep 2020 12:57:00

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:27

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:27

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:27

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'VISIT2'	System	31 Oct 2020 20:19:27

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:32

US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:35

US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:35

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Confirmed COVID-19 (COVID)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:49

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:52

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:52

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:52

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:52

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:57

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Oct 2020 13:20:46

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 13:20:46

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Heather Cherniawski	30 Oct 2020 15:10:13

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:13

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:13

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:	(b) (4)	
Data Entry Error	Heather Cherniawski	30 Oct 2020 17:46:25
User entered empty.	(b) (4)	
	Heather Cherniawski	30 Oct 2020 15:10:13
	(b) (4)	

US3812197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	30 Oct 2020 15:10:19

US3812197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 15:10:19

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Heather Cherniawski	30 Oct 2020 15:10:29

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:29

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:29

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:	(b) (4)	
Data Entry Error	Heather Cherniawski	30 Oct 2020 17:46:36
User entered empty.	(b) (4)	
	Heather Cherniawski	30 Oct 2020 15:10:29
	(b) (4)	

US3812197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	30 Oct 2020 15:10:36

US3812197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 15:10:36

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Heather Cherniawski	30 Oct 2020 15:10:45

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:45

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:10:45

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:	(b) (4)	
Data Entry Error	Heather Cherniawski	30 Oct 2020 17:46:48
User entered empty.	(b) (4)	
	Heather Cherniawski	30 Oct 2020 15:10:45
	(b) (4)	

US3812197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	30 Oct 2020 15:10:52

US3812197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 15:10:52

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered 'No (N)'	Heather Cherniawski	30 Oct 2020 15:11:30

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Heather Cherniawski	30 Oct 2020 15:11:30

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Heather Cherniawski	30 Oct 2020 15:11:30

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'VISIT3'	System	30 Oct 2020 15:11:30

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:14

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33

US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:17

US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:05:05
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:17

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 20:19:19

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:19

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 20:19:19

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered empty.	System	31 Oct 2020 20:19:19

US3812197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	30 Oct 2020 15:11:39

US3812197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 15:11:39

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 64'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:22:26
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 71'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-28T11:14:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af'	System	28 Oct 2020 16:14:18
User entered 'No (N)'	System	28 Oct 2020 16:14:18

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-28T11:14:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af'	System	28 Oct 2020 16:14:18
User entered 'No (N)'	System	28 Oct 2020 16:14:18

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-28T11:14:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af' User entered '28 Oct 2020 11:14:14'	System	28 Oct 2020 16:14:18
	System	28 Oct 2020 16:14:18

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 78'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-31T00:01:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd'	System	31 Oct 2020 05:01:28
User entered 'No (N)'	System	31 Oct 2020 05:01:28

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-31T00:01:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd'	System	31 Oct 2020 05:01:28
User entered 'No (N)'	System	31 Oct 2020 05:01:28

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-31T00:01:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd' User entered '31 Oct 2020 00:01:24'	System	31 Oct 2020 05:01:28
	System	31 Oct 2020 05:01:28

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered 'Day 92'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-18T11:53:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884'	System	18 Nov 2020 17:53:44
User entered 'No (N)'	System	18 Nov 2020 17:53:44

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-18T11:53:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884'	System	18 Nov 2020 17:53:44
User entered 'No (N)'	System	18 Nov 2020 17:53:44

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-18T11:53:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884' User entered '18 Nov 2020 11:53:42'	System	18 Nov 2020 17:53:44
	System	18 Nov 2020 17:53:44

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 17:34:22

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:50:58
Data entry locked.	System	17 Aug 2020 17:34:22
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 17:34:22

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-11-19T12:35:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d'	System	19 Nov 2020 18:35:56
User entered 'No (N)'	System	19 Nov 2020 18:35:56

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-11-19T12:35:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d'	System	19 Nov 2020 18:35:56
User entered 'No (N)'	System	19 Nov 2020 18:35:56

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-19T12:35:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d' User entered '19 Nov 2020 12:35:51'	System	19 Nov 2020 18:35:56
	System	19 Nov 2020 18:35:56

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-11-28T13:08:44', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '301f8de1-9e67-456e-ba21-f3f868b2e9b6'	System	28 Nov 2020 19:08:59
User entered 'No (N)'	System	28 Nov 2020 19:08:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-11-28T13:08:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '301f8de1-9e67-456e-ba21-f3f868b2e9b6'	System	28 Nov 2020 19:08:59
User entered 'No (N)'	System	28 Nov 2020 19:08:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-28T13:08:56', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '301f8de1-9e67-456e-ba21-f3f868b2e9b6'	System	28 Nov 2020 19:08:59
User entered '28 Nov 2020 13:08:56'	System	28 Nov 2020 19:08:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-12-02T00:03:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ba0b02af-9e88-42ae-984d-b5e8a7ab99dc'	System	02 Dec 2020 06:03:29
User entered 'No (N)'	System	02 Dec 2020 06:03:29

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-12-02T00:03:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ba0b02af-9e88-42ae-984d-b5e8a7ab99dc'	System	02 Dec 2020 06:03:29
User entered 'No (N)'	System	02 Dec 2020 06:03:29

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-12-02T00:03:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ba0b02af-9e88-42ae-984d-b5e8a7ab99dc'	System	02 Dec 2020 06:03:29
User entered '02 Dec 2020 00:03:27'	System	02 Dec 2020 06:03:29

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-12-11T13:23:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '02eefcb4-c3fa-4a75-8c72-086f015de275'	System	11 Dec 2020 19:23:17
User entered 'No (N)'	System	11 Dec 2020 19:23:17

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-12-11T13:23:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '02eefcb4-c3fa-4a75-8c72-086f015de275'	System	11 Dec 2020 19:23:17
User entered 'No (N)'	System	11 Dec 2020 19:23:17

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-12-11T13:23:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '02eefcb4-c3fa-4a75-8c72-086f015de275'	System	11 Dec 2020 19:23:17
User entered '11 Dec 2020 13:23:14'	System	11 Dec 2020 19:23:17

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-12-16T00:05:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4a309b1f-23ba-48d7-83ee-4b63d67d32e6'	System	16 Dec 2020 06:05:47
User entered 'No (N)'	System	16 Dec 2020 06:05:47

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-12-16T00:05:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4a309b1f-23ba-48d7-83ee-4b63d67d32e6'	System	16 Dec 2020 06:05:47
User entered 'No (N)'	System	16 Dec 2020 06:05:47

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-12-16T00:05:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4a309b1f-23ba-48d7-83ee-4b63d67d32e6'	System	16 Dec 2020 06:05:47
User entered '16 Dec 2020 00:05:45'	System	16 Dec 2020 06:05:47

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-12-23T19:24:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fa77ecc3-2212-455c-bd36-71e50cf9239e'	System	24 Dec 2020 01:24:13
User entered 'No (N)'	System	24 Dec 2020 01:24:13
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-12-23T19:24:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fa77ecc3-2212-455c-bd36-71e50cf9239e'	System	24 Dec 2020 01:24:13
User entered 'No (N)'	System	24 Dec 2020 01:24:13
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-12-23T19:24:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fa77ecc3-2212-455c-bd36-71e50cf9239e'	System	24 Dec 2020 01:24:13
User entered '23 Dec 2020 19:24:09'	System	24 Dec 2020 01:24:13
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2020-12-31T09:28:17', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '921cd686-cec2-4526-8aa7-ee30bd40bba7'	System	31 Dec 2020 15:28:38
User entered 'No (N)'	System	31 Dec 2020 15:28:38
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-12-31T09:28:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '921cd686-cec2-4526-8aa7-ee30bd40bba7'	System	31 Dec 2020 15:28:38
User entered 'No (N)'	System	31 Dec 2020 15:28:38
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-12-31T09:28:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '921cd686-cec2-4526-8aa7-ee30bd40bba7'	System	31 Dec 2020 15:28:38
User entered '31 Dec 2020 09:28:36'	System	31 Dec 2020 15:28:38
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-01-06T00:04:35', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ae6ae319-338c-44a7-9977-e4d01a1d6e2e'	System	06 Jan 2021 06:04:45
User entered 'No (N)'	System	06 Jan 2021 06:04:45
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-01-06T00:04:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ae6ae319-338c-44a7-9977-e4d01a1d6e2e'	System	06 Jan 2021 06:04:45
User entered 'No (N)'	System	06 Jan 2021 06:04:45
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-01-06T00:04:43', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ae6ae319-338c-44a7-9977-e4d01a1d6e2e'	System	06 Jan 2021 06:04:45
User entered '06 Jan 2021 00:04:43'	System	06 Jan 2021 06:04:45
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-01-13T09:10:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '8550e142-941e-4782-a6be-65392c39e442'	System	13 Jan 2021 15:10:17
User entered 'No (N)'	System	13 Jan 2021 15:10:17
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-01-13T09:10:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '8550e142-941e-4782-a6be-65392c39e442'	System	13 Jan 2021 15:10:17
User entered 'No (N)'	System	13 Jan 2021 15:10:17
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-01-13T09:10:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '8550e142-941e-4782-a6be-65392c39e442'	System	13 Jan 2021 15:10:17
User entered '13 Jan 2021 09:10:13'	System	13 Jan 2021 15:10:17
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-01-20T00:01:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4d83f932-2047-4766-b611-504077f1333f'	System	20 Jan 2021 06:01:42
User entered 'No (N)'	System	20 Jan 2021 06:01:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-01-20T00:01:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4d83f932-2047-4766-b611-504077f1333f'	System	20 Jan 2021 06:01:42
User entered 'No (N)'	System	20 Jan 2021 06:01:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-01-20T00:01:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '4d83f932-2047-4766-b611-504077f1333f'	System	20 Jan 2021 06:01:42
User entered '20 Jan 2021 00:01:30'	System	20 Jan 2021 06:01:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-01-28T09:03:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e97fbdcf-6a9d-47e0-9803-7ae9c4e01696'	System	28 Jan 2021 15:03:29
User entered 'No (N)'	System	28 Jan 2021 15:03:29
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-01-28T09:03:23', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e97fbdcf-6a9d-47e0-9803-7ae9c4e01696'	System	28 Jan 2021 15:03:29
User entered 'No (N)'	System	28 Jan 2021 15:03:29
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-01-28T09:03:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e97fbdcf-6a9d-47e0-9803-7ae9c4e01696'	System	28 Jan 2021 15:03:29
User entered '28 Jan 2021 09:03:25'	System	28 Jan 2021 15:03:29
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-02-06T17:59:49', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '197414d5-50a3-4df6-a26c-de362259b1ef'	System	06 Feb 2021 23:59:56
User entered 'No (N)'	System	06 Feb 2021 23:59:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-02-06T17:59:52', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '197414d5-50a3-4df6-a26c-de362259b1ef'	System	06 Feb 2021 23:59:56
User entered 'No (N)'	System	06 Feb 2021 23:59:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-02-06T17:59:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '197414d5-50a3-4df6-a26c-de362259b1ef'	System	06 Feb 2021 23:59:56
User entered '06 Feb 2021 17:59:54'	System	06 Feb 2021 23:59:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-02-13T09:26:23', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '255298da-b03f-4c59-80b5-5c12669bbd35'	System	13 Feb 2021 15:26:33
User entered 'No (N)'	System	13 Feb 2021 15:26:33
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-02-13T09:26:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '255298da-b03f-4c59-80b5-5c12669bbd35'	System	13 Feb 2021 15:26:33
User entered 'No (N)'	System	13 Feb 2021 15:26:33
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-02-13T09:26:29', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '255298da-b03f-4c59-80b5-5c12669bbd35'	System	13 Feb 2021 15:26:33
User entered '13 Feb 2021 09:26:29'	System	13 Feb 2021 15:26:33
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-02-20T11:51:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '97836cb0-2a75-4fb5-b264-5927d4defb9d'	System	20 Feb 2021 17:51:28
User entered 'No (N)'	System	20 Feb 2021 17:51:28
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-02-20T11:51:22', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '97836cb0-2a75-4fb5-b264-5927d4defb9d'	System	20 Feb 2021 17:51:28
User entered 'No (N)'	System	20 Feb 2021 17:51:28
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-02-20T11:51:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '97836cb0-2a75-4fb5-b264-5927d4defb9d'	System	20 Feb 2021 17:51:28
User entered '20 Feb 2021 11:51:25'	System	20 Feb 2021 17:51:28
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-02-26T16:11:02-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e027106c-b2c1-4e97-930c-44613873c761'	System	26 Feb 2021 22:11:10
User entered 'No (N)'	System	26 Feb 2021 22:11:10
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-02-26T16:11:05-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e027106c-b2c1-4e97-930c-44613873c761'	System	26 Feb 2021 22:11:10
User entered 'No (N)'	System	26 Feb 2021 22:11:10
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-02-26T16:11:08-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e027106c-b2c1-4e97-930c-44613873c761'	System	26 Feb 2021 22:11:10
User entered '26 Feb 2021 16:11:08'	System	26 Feb 2021 22:11:10
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-03-03T09:31:22-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ff0d038f-953c-41c0-b974-8d2baa81cfd2'	System	03 Mar 2021 15:31:30
User entered 'No (N)'	System	03 Mar 2021 15:31:30
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-03-03T09:31:25-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ff0d038f-953c-41c0-b974-8d2baa81cfd2'	System	03 Mar 2021 15:31:30
User entered 'No (N)'	System	03 Mar 2021 15:31:30
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-03T09:31:27-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'ff0d038f-953c-41c0-b974-8d2baa81cfd2'	System	03 Mar 2021 15:31:30
User entered '03 Mar 2021 09:31:27'	System	03 Mar 2021 15:31:30
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-03-13T10:23:17-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '182cda77-5b16-4d59-bd82-b97e87a0fcd9'	System	13 Mar 2021 16:23:25
User entered 'No (N)'	System	13 Mar 2021 16:23:25
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-03-13T10:23:19-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '182cda77-5b16-4d59-bd82-b97e87a0fcd9'	System	13 Mar 2021 16:23:25
User entered 'No (N)'	System	13 Mar 2021 16:23:25
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-13T10:23:21-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '182cda77-5b16-4d59-bd82-b97e87a0fcd9'	System	13 Mar 2021 16:23:25
User entered '13 Mar 2021 10:23:21'	System	13 Mar 2021 16:23:25
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-03-20T10:25:48-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fc58eeb4-d414-47ae-a8cf-8a8a11a6832b'	System	20 Mar 2021 15:25:56
User entered 'No (N)'	System	20 Mar 2021 15:25:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-20T10:25:51-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fc58eeb4-d414-47ae-a8cf-8a8a11a6832b'	System	20 Mar 2021 15:25:56
User entered 'No (N)'	System	20 Mar 2021 15:25:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-20T10:25:53-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fc58eeb4-d414-47ae-a8cf-8a8a11a6832b'	System	20 Mar 2021 15:25:56
User entered '20 Mar 2021 10:25:53'	System	20 Mar 2021 15:25:56
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-03-24T01:49:45-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '7c6469d0-bdc4-4046-bab5-26f9d2733530'	System	24 Mar 2021 06:49:51
User entered 'No (N)'	System	24 Mar 2021 06:49:51
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-03-24T01:49:47-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '7c6469d0-bdc4-4046-bab5-26f9d2733530'	System	24 Mar 2021 06:49:51
User entered 'No (N)'	System	24 Mar 2021 06:49:51
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-24T01:49:49-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '7c6469d0-bdc4-4046-bab5-26f9d2733530'	System	24 Mar 2021 06:49:51
User entered '24 Mar 2021 01:49:49'	System	24 Mar 2021 06:49:51
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-04-03T11:40:34-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b5a3c1a-af6b-417a-80b7-1bab16f605b5'	System	03 Apr 2021 16:40:42
User entered 'No (N)'	System	03 Apr 2021 16:40:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-04-03T11:40:36-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b5a3c1a-af6b-417a-80b7-1bab16f605b5'	System	03 Apr 2021 16:40:42
User entered 'No (N)'	System	03 Apr 2021 16:40:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-04-03T11:40:39-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b5a3c1a-af6b-417a-80b7-1bab16f605b5'	System	03 Apr 2021 16:40:42
User entered '03 Apr 2021 11:40:39'	System	03 Apr 2021 16:40:42
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-04-07T01:42:24-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5cd9e84-43f9-4ffd-be4f-b05cc925735e'	System	07 Apr 2021 06:42:35
User entered 'No (N)'	System	07 Apr 2021 06:42:35
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-04-07T01:42:26-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5cd9e84-43f9-4ffd-be4f-b05cc925735e'	System	07 Apr 2021 06:42:35
User entered 'No (N)'	System	07 Apr 2021 06:42:35
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-04-07T01:42:28-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5cd9e84-43f9-4ffd-be4f-b05cc925735e'	System	07 Apr 2021 06:42:35
User entered '07 Apr 2021 01:42:28'	System	07 Apr 2021 06:42:35
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-04-17T17:23:32-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '46dc721b-29ce-493c-be85-b1bb46c92d30'	System	17 Apr 2021 22:23:41
User entered 'No (N)'	System	17 Apr 2021 22:23:41
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-04-17T17:23:34-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '46dc721b-29ce-493c-be85-b1bb46c92d30'	System	17 Apr 2021 22:23:41
User entered 'No (N)'	System	17 Apr 2021 22:23:41
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-04-17T17:23:37-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '46dc721b-29ce-493c-be85-b1bb46c92d30'	System	17 Apr 2021 22:23:41
User entered '17 Apr 2021 17:23:37'	System	17 Apr 2021 22:23:41
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-04-21T08:14:32-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '41a469ed-e4de-495f-84df-9561fc435b47'	System	21 Apr 2021 13:14:39
User entered 'No (N)'	System	21 Apr 2021 13:14:39
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-04-21T08:14:34-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '41a469ed-e4de-495f-84df-9561fc435b47'	System	21 Apr 2021 13:14:39
User entered 'No (N)'	System	21 Apr 2021 13:14:39
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-04-21T08:14:37-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '41a469ed-e4de-495f-84df-9561fc435b47'	System	21 Apr 2021 13:14:39
User entered '21 Apr 2021 08:14:37'	System	21 Apr 2021 13:14:39
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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 (ed0c9a0365387b00)', Time: '2021-04-28T08:46:33-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c4791218-2ae0-4010-9d66-adbf88f4e1b2'	System	29 Apr 2021 01:04:43
User entered 'No (N)'	System	29 Apr 2021 01:04:43
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2021-04-28T08:46:38-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c4791218-2ae0-4010-9d66-adbf88f4e1b2'	System	29 Apr 2021 01:04:43
User entered 'No (N)'	System	29 Apr 2021 01:04:43
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-04-28T08:46:41-05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c4791218-2ae0-4010-9d66-adbf88f4e1b2'	System	29 Apr 2021 01:04:43
User entered '28 Apr 2021 08:46:41'	System	29 Apr 2021 01:04:43
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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DataPoint Activated.	System	16 Dec 2020 23:33:06
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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

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Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

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DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Date and time of submission](#)

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DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

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Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
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US3812197

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
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US3812197

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Have you been exposed to someone with 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)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:22:26

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Dec 2020 23:33:06
DataPoint Inactivated.	System	16 Dec 2020 23:30:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:22:26
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:22:26

US3812197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:34:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-03T09:31:36-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '252f7af6-4c2f-4b25-a83f-bca9efcae3f8'	System	03 Mar 2021 15:31:48
User entered 'No (N)'	System	03 Mar 2021 15:31:48

US3812197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:34:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2021-03-03T09:31:45-06:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '252f7af6-4c2f-4b25-a83f-bca9efcae3f8'	System	03 Mar 2021 15:31:48
User entered '03 Mar 2021 09:31:45'	System	03 Mar 2021 15:31:48

US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'No (N)'	Heather Cherniawski	30 Oct 2020 15:12:42

US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:12:42

US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	30 Oct 2020 15:12:42

US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:	(b) (4)	
Data Entry Error	Heather Cherniawski	30 Oct 2020 17:46:59
User entered empty.	(b) (4)	
	Heather Cherniawski	30 Oct 2020 15:12:42
	(b) (4)	

US3812197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	30 Oct 2020 15:12:52

US3812197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:35:33
User entered 'I'	System	30 Oct 2020 15:12:52

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Nov 2020 19:43:41

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:33:06
User entered '13 Nov 2020'	System	16 Dec 2020 23:30:25
	Karen Knapp (b) (4)	13 Nov 2020 19:43:41
	(b) (4)	

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	13 Nov 2020 19:43:41

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Karen Knapp (b) (4)	13 Nov 2020 19:43:41

US3812197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Nov 2020 19:43:47

US3812197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User entered 'I'	System	13 Nov 2020 19:43:47

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Dec 2020 21:03:05

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:33:06
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
User entered '15 Dec 2020'	Karen Knapp (b) (4)	15 Dec 2020 21:03:05

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	15 Dec 2020 21:03:05

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Karen Knapp (b) (4)	15 Dec 2020 21:03:05

US3812197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Dec 2020 21:03:10

US3812197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User entered 'I'	System	15 Dec 2020 21:03:10

US3812197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Jan 2021 23:20:15

US3812197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '13 Jan 2021'	Karen Knapp (b) (4)	13 Jan 2021 23:20:15

US3812197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	13 Jan 2021 23:20:15

US3812197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Karen Knapp (b) (4)	13 Jan 2021 23:20:15

US3812197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Jan 2021 23:20:19

US3812197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:55:16
User entered 'I'	System	13 Jan 2021 23:20:19

US3812197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:31
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:31
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:31
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'VISIT4'	System	26 Mar 2021 21:29:31

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16:13'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered '25 Mar 2021 16:13'	System	02 Apr 2021 20:05:20

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '97.3' F	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '76'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'bpm'	System	02 Apr 2021 20:05:20

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'breaths/min'	System	02 Apr 2021 20:05:20

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '122'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'mmHg'	System	02 Apr 2021 20:05:20

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '74'	Breanna Galibert (b) (4)	02 Apr 2021 20:05:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'mmHg'	System	02 Apr 2021 20:05:20

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47

US3812197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47

US3812197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:37
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	26 Mar 2021 21:29:37
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:41
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:41
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16:25'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:41
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered '25 Mar 2021 16:25'	System	26 Mar 2021 21:29:41

US3812197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Mar 2021 17:32:20
	(b) (4)	

US3812197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:46:47
User entered 'I'	System	13 Mar 2021 17:32:20

US3812197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Mar 2021 17:32:50
	(b) (4)	

US3812197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '13 Mar 2021'	Karen Knapp (b) (4)	13 Mar 2021 17:32:50
	(b) (4)	

US3812197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	13 Mar 2021 17:32:50
	(b) (4)	

US3812197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	13 Mar 2021 17:32:50
	(b) (4)	

US3812197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Mar 2021 17:32:56
	(b) (4)	

US3812197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:18:18
User entered 'I'	System	13 Mar 2021 17:32:56

US3812197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Yes (Y)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:15:18

US3812197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered '16 Apr 2021'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:15:18

US3812197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:15:18

US3812197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered empty.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:15:18

US3812197

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Yes (Y)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:15:25

US3812197

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:15:25

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:50

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:36:54
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:21:39
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:36:54
User entered '17:20'	Karen Knapp (b) (4)	02 Sep 2020 20:21:39
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:04
User entered '27 Aug 2020 17:20'	System	02 Sep 2020 20:21:39

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:36:54
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Karen Knapp (b) (4)	02 Sep 2020 20:21:39
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:36:54
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Sep 2020 20:21:39
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 4 (Day 4)' reason for change: New Information	Breanna Galibert (b) (4)	19 Oct 2020 16:04:47
	(b) (4)	
User entered 'Day 1 (Day 1)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '99'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:23:08

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:49:30
	(b) (4)	
User closed query 'Please not symptom stopped on 26Aug20' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 15:49:28
	(b) (4)	
Query 'Please not symptom stopped on 26Aug20' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4)	22 Oct 2020 18:56:03
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	22 Oct 2020 18:55:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 18:55:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User opened query 'Please not symptom stopped on 26Aug20' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:45:17
	(b) (4)	
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:49:35
	(b) (4)	
User closed query 'Please not symptom stopped on 26Aug20' (Site from CRA).	(b) (4)	30 Oct 2020 15:49:32
Query 'Please not symptom stopped on 26Aug20' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4)	22 Oct 2020 18:56:07
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	22 Oct 2020 18:55:36
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 18:55:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User opened query 'Please not symptom stopped on 26Aug20' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:44:30
	(b) (4)	
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:23:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 5 (Day 5)' reason for change: New Information	Breanna Galibert (b) (4)	19 Oct 2020 16:05:35
	(b) (4)	
User entered 'Day 2 (Day 2)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '28 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:24:18

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.7' F	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:18
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 6 (Day 6)' reason for change: New Information	Breanna Galibert (b) (4)	19 Oct 2020 16:07:39
	(b) (4)	
User entered 'Day 3 (Day 3)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '29 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '99'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:24:55

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.7' F	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:24:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:08:14
New Information	(b) (4)	
User entered 'Day 4 (Day 4)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '30 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '96'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:25:50

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.7' F	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:25:50
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:08:40
New Information	(b) (4)	
User entered 'Day 5 (Day 5)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '31 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '99'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:26:25

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.7' F	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:25
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 9 (Day 9)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:09:37
New Information	(b) (4)	
User entered 'Day 6 (Day 6)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:57:47
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:02:46
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:02:46
	(b) (4)	
User entered '01 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:02:46
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '1 Sep 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	02 Sep 2020 20:26:49

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '96.8' F	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	02 Sep 2020 20:26:49
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:10:10
New Information	(b) (4)	
User entered 'Day 7 (Day 7)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:57:55
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:04:31
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:04:31
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:04:31
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '2 Sep 2020'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '99'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	06 Sep 2020 21:59:08

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '98' F	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:08
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 11 (Day 11)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:10:50
New Information	(b) (4)	
User entered 'Day 8 (Day 8)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lylv Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:02
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:05:23
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:05:23
	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:05:23
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '3 Sep 2020'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	06 Sep 2020 21:59:44

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 21:59:44
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 12 (Day 12)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:11:18
New Information	(b) (4)	
User entered 'Day 9 (Day 9)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:09
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:06:14
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:06:14
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:06:14
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '4 Sep 2020'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '98'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	06 Sep 2020 22:00:09

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Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Form: Symptom Log (9)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 22:00:09
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 13 (Day 13)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:11:49
New Information	(b) (4)	
User entered 'Day 10 (Day 10)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:42:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:14
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:13:33
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:13:33
	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:13:33
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '5 Sep 2020'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '99'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	07 Sep 2020 17:30:13

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Form: Symptom Log (10)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '98.1' F	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:13
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 14 (Day 14)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:12:26
New Information	(b) (4)	
User entered 'Day 11 (Day 11)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:42:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:19
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 17:15:11
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 17:15:11
User entered '06 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 17:15:11
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '6 Sep 2020'	Karen Knapp (b) (4) (b) (4)	07 Sep 2020 17:30:39

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	07 Sep 2020 17:30:39

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Karen Knapp (b) (4)	07 Sep 2020 17:30:39
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 15 (Day 15)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:12:51
New Information	(b) (4)	
User entered 'Day 12 (Day 12)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:29
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:15:45
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:15:45
	(b) (4)	
User entered '07 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:15:45
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '7 Sep 2020'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	09 Sep 2020 02:58:29

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:58:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 16 (Day 16)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:13:15
New Information	(b) (4)	
User entered 'Day 13 (Day 13)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:42:32
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:58:33
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	08 Apr 2021 17:16:25
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	08 Apr 2021 17:16:25
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	08 Apr 2021 17:16:25
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '8 Sep 2020'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	09 Sep 2020 02:59:33

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.8' F	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	09 Sep 2020 02:59:33
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 17 (Day 17)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:13:41
New Information	(b) (4)	
User entered 'Day 14 (Day 14)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '09 Sep 2020'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '98'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	11 Sep 2020 02:38:42

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.6' F	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Heather Cherniawski	11 Sep 2020 02:38:42
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 18 (Day 18)' reason for change:	Breanna Galibert (b) (4)	19 Oct 2020 16:14:30
New Information	(b) (4)	
User entered 'Day 15 (Day 15)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
required.	(b) (4)	
DataPoint inactivated with code reason code Data not	(b) (4), (b) (6)	11 Sep 2020 18:38:35
required.		

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
Query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 29SEP2020. Please reconcile' canceled (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:19:14
User opened query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 29SEP2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:46:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '10 Sep 2020'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '100'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	16 Sep 2020 22:27:13
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '97.4' F	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
DataPoint activated with code reason code Data required.	(b) (4) Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	16 Sep 2020 22:27:13
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	16 Sep 2020 22:23:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Sep 2020 18:38:35

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered '24 Aug 2020'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Per CDM : Please consider recording Not Done for Days 1-3 (O2 Saturation and Temperature)' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:26:51
Query 'Per CDM : Please consider recording Not Done for Days 1-3 (O2 Saturation and Temperature)' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	18 Jan 2021 18:31:59
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
User opened query 'Per CDM : Please consider recording Not Done for Days 1-3 (O2 Saturation and Temperature)' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 20:45:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	18 Jan 2021 18:31:44
User entered empty.	System	19 Oct 2020 15:16:31
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
	(b) (4)	
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
DataPoint activated with code reason code Data required.	(b) (4) Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
DataPoint inactivated with code reason code Data not required.	(b) (4) Breanna Galibert (b) (4)	16 Sep 2020 22:24:34

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:16:31
	(b) (4)	
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	19 Oct 2020 15:15:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	16 Sep 2020 22:24:34
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '25 Aug 2020'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	18 Jan 2021 18:31:44
User entered empty.	System	19 Oct 2020 15:17:46

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:24:20
DataPoint Un-verified.		16 Nov 2020 16:24:09
DataPoint Verified.		21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 15:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '26 Aug 2020'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered '0'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User entered '%'	System	18 Jan 2021 18:31:44
User entered empty.	System	19 Oct 2020 16:03:55

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:03:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 18:31:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:00:08
Query 'Please clarify as there is not an end date noted in the Source. ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:00:05
User opened query 'Please clarify as there is not an end date noted in the Source. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:00:26
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:59:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

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Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:43:00
User closed query 'Please note for Nasal Congestion and Runny Nose, the end date is noted as 26Aug2020. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 20:42:56
Query 'Please note for Nasal Congestion and Runny Nose, the end date is noted as 26Aug2020. ' answered with 'AS STATED END DATE IS NOTED AS 26AUG2020 SO INFORMATION PROVIDED IS CORRECT' (Site from CRA).	Breanna Galibert (b) (4)	06 Apr 2021 20:09:04
User opened query 'Please note for Nasal Congestion and Runny Nose, the end date is noted as 26Aug2020. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:59:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:59:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:34:50

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:12
User entered 'None (None)'	Breanna Galibert (b) (4)	19 Oct 2020 16:03:55
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Date of Visit is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:53
User opened query 'Date of Visit is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		11 Sep 2020 18:00:52
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive' (Site from System).	Karen Knapp (b) (4)	02 Sep 2020 20:28:06
	(b) (4)	
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	02 Sep 2020 20:27:41
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:53
User opened query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:50

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:29
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:27:41
	(b) (4)	

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:19
User entered 'I'	System	02 Sep 2020 20:27:41

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Generated On: 12 Aug 2021 13:34:50

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:35:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:35:46
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	02 Sep 2020 20:35:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:35:21
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:57:53
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:35:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:35:46
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:35:46
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:35:21
User entered empty.	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:35:21

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:34:50

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Generated On: 12 Aug 2021 13:34:50

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:04:04
Query 'Per CDM: It appears that both 'Did the subject Angie Kean have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly.	(b) (4)	16 Feb 2021 16:14:20
' answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 05:49:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Generated On: 12 Aug 2021 13:34:50

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:11
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	16 Feb 2021 16:14:15
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:13
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	16 Feb 2021 16:14:15
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:15
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	16 Feb 2021 16:14:15
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Per CDM: Please consider completing Evidence of Shock and Evidence of Pneumonia as there are missing responses.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 13:53:20
Query 'Per CDM: Please consider completing Evidence of Shock and Evidence of Pneumonia as there are missing responses.' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	19 Jan 2021 22:25:07
	(b) (4)	
User opened query 'Per CDM: Please consider completing Evidence of Shock and Evidence of Pneumonia as there are missing responses.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 18:25:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21

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Folder: Covid-19 Assessment 27 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:05:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Un-verified.	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 22:24:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered 'No (N)'	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:53
User entered empty.	Karen Knapp (b) (4)	02 Sep 2020 20:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:34:50

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:12:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:57:58
User entered 'No (N)'	Karen Knapp (b) (4)	18 Oct 2020 12:58:47
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 3 (Day 3)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered '29 Aug 2020'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 5 (Day 5)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered '31 Aug 2020'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 7 (Day 7)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 10:12:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA IS CORRECT. PPD NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:20:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:53:29
Query 'Per GCL Lab Recon: GCL has Saliva Day 7, Day 9, Day 14, and Day 21 with dates of 01SEP2020, 03SEP2020, 09SEP2020 and 16SEP2020 respectively. Please reconcile or clarify' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:51:16
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 7, Day 9, Day 14, and Day 21 with dates of 01SEP2020, 03SEP2020, 09SEP2020 and 16SEP2020 respectively. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 19:54:01
User entered '2 Sep 2020'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 9 (Day 9)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:52:13
Query 'please verify lab in source & lab portal, specimen was drawn on 3SEP. ' canceled (Site from CRA).		16 Nov 2020 16:52:12
User opened query 'please verify lab in source & lab portal, specimen was drawn on 3SEP. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 16:46:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:12:31
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:56:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA IS CORRECT. PPD NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Oct 2020 19:24:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:54:02
User entered '4 Sep 2020'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 14 (Day 14)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	22 Oct 2020 18:58:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:02:39
Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System).	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:42
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:24:08
User entered empty.	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered '09 Sep 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 18:58:17
User entered empty.	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 21 (Day 21)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	22 Oct 2020 18:58:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:02:54
Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System).	Heather Cherniawski (b) (4)	07 Sep 2020 19:25:02
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:24:08
User entered empty.	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered '16 Sep 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	22 Oct 2020 18:58:31
User entered empty.	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User accepted default value 'Day 28 (Day 28)'	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	22 Oct 2020 18:58:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:03:20
Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System).	Heather Cherniawski (b) (4)	07 Sep 2020 19:25:19
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 19:24:08
User entered empty.	Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:15:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:56:07
User entered '29 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	22 Oct 2020 18:58:45
User entered empty.	(b) (4) Heather Cherniawski (b) (4)	07 Sep 2020 19:24:08

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:06
Query 'Please complete unscheduled visit to capture day 1 illness visit and NP swab.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Oct 2020 00:37:06
User opened query 'Please complete unscheduled visit to capture day 1 illness visit and NP swab.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 18:25:34
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:29:25

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	16 Dec 2020 23:31:53
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:58:06
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:29:25
	(b) (4)	

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:06
User entered 'Clinic (Clinic)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:29:25

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:40
User entered 'SICKD1'	System	02 Sep 2020 20:29:25

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:53
DataPoint Verified.	System	16 Dec 2020 23:30:25
User entered '27 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:58:23
	Karen Knapp (b) (4)	02 Sep 2020 20:30:38
	(b) (4)	

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '17:29'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User entered '27 Aug 2020 17:29'	System	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '97.8' F	Karen Knapp (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered empty.	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '77'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User entered 'bpm'	System	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '16'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User entered 'breaths/min'	System	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '112'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User entered 'mmHg'	System	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:23
User entered '76'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50
User entered 'mmHg'	System	02 Sep 2020 20:30:38

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:50

US3812197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:32
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:30:52

US3812197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:13:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	16 Dec 2020 23:31:53
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:58:32
User entered '27 Aug 2020'	Karen Knapp (b) (4)	02 Sep 2020 20:30:52
	(b) (4)	

US3812197

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:34:50

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:57
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:31:21

US3812197

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:58:57
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:31:21

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:34:01

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	16 Dec 2020 23:33:06
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:35
User entered '29 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 13:34:37
User entered '30 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	30 Sep 2020 13:34:01
	(b) (4)	

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:35
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:34:01

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:15
User entered 'SICKD28'	System	30 Sep 2020 13:34:01

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:33:06
DataPoint Verified.	System	16 Dec 2020 23:30:25
User entered '29 Sep 2020'	(b) (4), (b) (6)	21 Oct 2020 18:59:58
	Breanna Galibert (b) (4)	30 Sep 2020 13:35:22
	(b) (4)	

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '11:05'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User entered '29 Sep 2020 11:05'	System	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '62'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User entered 'bpm'	System	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '12'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User entered 'breaths/min'	System	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '118'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User entered 'mmHg'	System	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:59:58
User entered '72'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26
User entered 'mmHg'	System	30 Sep 2020 13:35:22

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:26

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:00:07
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:35:32

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:00:07
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	30 Sep 2020 13:35:32
	(b) (4)	

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:34:50

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:00:25
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:36:20

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:34:50

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:14:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:00:25
User entered '29 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 13:36:20

US3812197

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:54:38

US3812197

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:54:38

US3812197

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Clinic (Clinic)'	Heather Cherniawski	28 Jan 2021 15:54:38

US3812197

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 15:54:38

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:36:41
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:54:50

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 16:36:41
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:54:50

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Placebo (Placebo)'	Heather Cherniawski (b) (4)	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Placebo (Placebo)'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Placebo (Placebo)'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'I'	System	28 Jan 2021 15:55:29

US3812197

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'I'	System	28 Jan 2021 15:55:29

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '68.7' in	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '192.8' lb	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28.78084'	System	28 Jan 2021 16:00:58
DataPoint set to visible.	System	28 Jan 2021 15:55:29

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '68.7' in	Heather Cherniawski	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '192.8' lb	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28.78084'	System	28 Jan 2021 16:00:58
DataPoint set to visible.	System	28 Jan 2021 15:55:29

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '09:10'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28 Jan 2021 09:10'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '98.3' F	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Oral (Oral)'	Heather Cherniawski	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '66'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'bpm'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '14'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'breaths/min'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '112'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'mmHg'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '72'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'mmHg'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '68.7' in	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '192.8' lb	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28.78084'	System	28 Jan 2021 16:00:58
DataPoint set to visible.	System	28 Jan 2021 15:55:29

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '10:15'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28 Jan 2021 10:15'	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 17:37:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 17:37:36
User entered '97.5' F reason for change: Data Entry Error	Heather Cherniawski (b) (4)	28 Jan 2021 17:37:36
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 16:00:58
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 17:37:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 17:37:36
User entered '58' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	28 Jan 2021 17:37:36
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 16:00:58
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'bpm'	System	28 Jan 2021 17:37:36
User entered empty.	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 17:37:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 17:37:36
User entered '12' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	28 Jan 2021 17:37:36
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 16:00:58
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'breaths/min'	System	28 Jan 2021 17:37:36
User entered empty.	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 17:37:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 17:37:36
User entered '118' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	28 Jan 2021 17:37:36
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 16:00:58
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'mmHg'	System	28 Jan 2021 17:37:36
User entered empty.	System	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Jan 2021 17:37:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	28 Jan 2021 17:37:36
User entered '74' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	28 Jan 2021 17:37:36
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 16:00:58
User entered empty.	Heather Cherniawski (b) (4)	28 Jan 2021 16:00:58

US3812197

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'mmHg'	System	28 Jan 2021 17:37:36
User entered empty.	System	28 Jan 2021 16:00:58

US3812197

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Jan 2021 15:59:36

US3812197

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski (b) (4)	28 Jan 2021 15:59:36

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'mRNA-1273'	System	28 Jan 2021 15:59:09
DataPoint set to visible.	System	28 Jan 2021 15:55:29

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '09:44'	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28 Jan 2021 09:44'	System	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'ONCE'	System	28 Jan 2021 15:59:09

US3812197

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 15:59:09

US3812197

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:58:40

US3812197

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:58:40

US3812197

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '09:20'	Heather Cherniawski	28 Jan 2021 15:58:40

US3812197

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28 Jan 2021 09:20'	System	28 Jan 2021 15:58:40

US3812197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:58:12

US3812197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '28 Jan 2021'	Heather Cherniawski	28 Jan 2021 15:58:12

US3812197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered '09:25'	Heather Cherniawski	28 Jan 2021 15:58:12

US3812197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered '28 Jan 2021 09:25'	System	28 Jan 2021 15:58:12

US3812197

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

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered 'Yes (Y)'	Heather Cherniawski	28 Jan 2021 15:57:38

US3812197

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

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:31
User entered 'I'	System	28 Jan 2021 15:57:38

US3812197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 15:32:54
	(b) (4)	

US3812197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '04 Feb 2021'	Breanna Galibert (b) (4)	01 Mar 2021 15:32:54
	(b) (4)	

US3812197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	01 Mar 2021 15:33:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	01 Mar 2021 15:32:54
	(b) (4)	

US3812197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'left message to call back' reason for change: Data Entry Error	Breanna Galibert (b) (4)	01 Mar 2021 15:33:14
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	01 Mar 2021 15:32:54
	(b) (4)	

US3812197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 15:33:01
	(b) (4)	

US3812197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User entered 'I'	System	01 Mar 2021 15:33:01

US3812197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:34:45
User entered 'I'	System	01 Mar 2021 15:33:01
DataPoint set to visible.	System	01 Mar 2021 15:33:01

US3812197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:33:33

US3812197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:33:33

US3812197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:33:33

US3812197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'OLD29'	System	01 Mar 2021 15:33:33

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '15:51'	Breanna Galibert (b) (4)	01 Mar 2021 15:35:36
	(b) (4)	

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered '26 Feb 2021 15:51'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '97.9' F	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '64'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'bpm'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '14'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'breaths/min'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '100'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'mmHg'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '64'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'mmHg'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '16:33'	Breanna Galibert (b) (4)	01 Mar 2021 15:35:36
	(b) (4)	

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered '26 Feb 2021 16:33'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '62'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'bpm'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '12'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'breaths/min'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '118'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'mmHg'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '82'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:36:59
User entered 'mmHg'	System	01 Mar 2021 15:35:36

US3812197

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:26

US3812197

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:26

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User entered 'mRNA-1273'	System	01 Mar 2021 15:34:41
DataPoint set to visible.	System	01 Mar 2021 15:33:01

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered '16:02'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User entered '26 Feb 2021 16:02'	System	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User entered 'ONCE'	System	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 15:34:41

US3812197

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:53:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Mar 2021 15:34:43

US3812197

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:35:16
User entered 'I'	System	01 Mar 2021 15:34:43

US3812197

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Mar 2021 17:49:46
	(b) (4)	

US3812197

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered '6 Mar 2021'	Karen Knapp (b) (4)	06 Mar 2021 17:49:46
	(b) (4)	

US3812197

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	06 Mar 2021 17:49:46
	(b) (4)	

US3812197

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	06 Mar 2021 17:49:46
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:53:44
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Mar 2021 17:49:51
	(b) (4)	

US3812197

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:12
User entered 'I'	System	06 Mar 2021 17:49:51

US3812197

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	26 Mar 2021 21:28:52
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	26 Mar 2021 21:28:52
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	26 Mar 2021 21:28:52
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered 'OLD57'	System	26 Mar 2021 21:28:52

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16:13'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered '25 Mar 2021 16:13'	System	26 Mar 2021 21:29:08

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '97.3' F	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '76'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered 'bpm'	System	26 Mar 2021 21:29:08

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered 'breaths/min'	System	26 Mar 2021 21:29:08

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '122'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered 'mmHg'	System	26 Mar 2021 21:29:08

US3812197

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '74'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:08
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered 'mmHg'	System	26 Mar 2021 21:29:08

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49

US3812197

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:10
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	26 Mar 2021 21:29:10
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:20
	(b) (4)	

US3812197

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '25 Mar 2021'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:20
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:38:43
	(b) (4)	
User entered '16:25'	Breanna Galibert (b) (4)	26 Mar 2021 21:29:20
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:18:49
User entered '25 Mar 2021 16:25'	System	26 Mar 2021 21:29:20

US3812197

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:34:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:02:35
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:46:18

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	21 Oct 2020 19:09:25
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:27:31
User entered	System	01 Sep 2020 18:27:10
'USA-US111-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	01 Sep 2020 18:27:10

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:54:26
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:17
Data point term sent to Coder	System	23 Nov 2020 20:59:22
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:03
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:23:54
' (Site from System).		
User closed query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:19:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:30:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:30:06
Query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.'	Lyly Dang (b) (4)	20 Nov 2020 17:15:00
answered with 'updated' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	20 Nov 2020 17:14:42

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Lyly Dang (b) (4) (b) (4)	20 Nov 2020 17:13:45
Coding entries removed.	Lyly Dang (b) (4) (b) (4)	20 Nov 2020 17:13:45
User entered 'Symptomatic COVID-19' reason for change: Per Query Resolution	Lyly Dang (b) (4) (b) (4)	20 Nov 2020 17:13:45
User opened query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:25:49
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 02:47:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 02:47:55
Data point term sent to Coder	System	11 Sep 2020 02:46:23
Coding entries removed.	Heather Cherniawski (b) (4)	11 Sep 2020 02:45:42
User entered 'COVID-19' reason for change: Per Query Resolution	Heather Cherniawski (b) (4)	11 Sep 2020 02:45:42
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 PCR test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:22:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:22:47
Data point term sent to Coder	System	01 Sep 2020 12:49:47
User entered 'Covid-19 PCR Swab Positive'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User closed query 'PV Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:48:32
Query 'PV Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' answered with 'EDC updated' (Site from Safety).	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:58
User opened query 'PV Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 18:37:58
Query 'Safety Medical Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 18:37:34

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User opened query 'Safety Medical Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety). User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:52:48
	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered 'No (N)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:53
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:59:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:09:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User closed query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).	(b) (4), (b) (6)	12 Sep 2020 16:56:17
Query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' answered with 'UPDATED PER QUERY' (Site from Safety).	Heather Cherniawski (b) (4)	11 Sep 2020 02:48:59
User entered '24 Aug 2020' reason for change: Per Query Resolution	Heather Cherniawski (b) (4)	11 Sep 2020 02:45:42
User opened query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 11:05:05
Query 'Safety Medical Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' canceled (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 11:04:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Safety Medical Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 11:04:34
User closed query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 20:31:22
Query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' answered with 'completed' (Site from CRA).	Karen Knapp (b) (4)	02 Sep 2020 20:28:57
User opened query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 14:51:16
User entered '27 Aug 2020'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:04:06
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 16:25:02
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:54:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	31 Mar 2021 18:29:42
DataPoint Un-verified.	Lyly Dang (b) (4) (b) (4)	31 Mar 2021 18:29:33
Signature has been broken.	Lyly Dang (b) (4) (b) (4)	31 Mar 2021 18:29:33
User entered '28 Aug 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	31 Mar 2021 18:29:33
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:04:08
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until information is available.' canceled (Site from Safety).		08 Oct 2020 17:41:01
User entered '26 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 16:25:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 10:53:27
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:44:16
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'WILL UPDATE WHEN AVAILABLE' (Site from Safety).	Karen Knapp (b) (4) (b) (4)	05 Sep 2020 21:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	03 Sep 2020 11:18:38
	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:04:10
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:52:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:51:57
User entered empty.	System	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:04:12
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Lyly Dang (b) (4)	16 Sep 2020 19:18:08
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Sep 2020 16:26:17
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Cherniawski	01 Sep 2020 12:48:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:06:11
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Oct 2020 23:00:14
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Oct 2020 22:55:43
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:55:43
User closed query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:19:37
Query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment.' answered with 'Severity was changed from Grade 1 to Grade 3 due to subject needing to quarantine and undergo daily telehealth visits by the clinic' (Site from Safety).	Lyly Dang (b) (4) (b) (4)	14 Sep 2020 16:28:09
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Sep 2020 02:48:32
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Sep 2020 02:45:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	11 Sep 2020 02:45:42
User opened query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 11:01:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:06:13
User entered '0'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:06:14
User entered '0'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:06:16
User entered '0'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:06:18
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered '0'	Heather Cherniawski	01 Sep 2020 12:48:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered '0'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered '0' reason for change: New Information	Lyly Dang (b) (4)	18 Oct 2020 23:00:14
	(b) (4)	
User entered '1' reason for change: New Information	Heather Cherniawski	11 Sep 2020 02:48:32
	(b) (4)	
User entered '0'	Heather Cherniawski	01 Sep 2020 12:48:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 07:49:55
Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' answered with 'IP does not contain COVID-19 in vaccine ' (Site from DM).	Lyly Dang (b) (4) (b) (4)	22 Oct 2020 22:22:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:45:14
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	09 Sep 2020 02:27:07
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	07 Sep 2020 19:42:37
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per DM CLR - RQ: Site's response "Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Subject received IP dose #1 on 17 Aug 2020. Subject does not qualify to receive Dose 2; therefore, IP withdrawn" noted. However, this is not reflected in CCG page 38-39. Please review and ensure that the date of discontinuation reflects when the decision to discontinue the Treatment was established. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:59:07
Query 'Per DM CLR - RQ: Site's response "Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Subject received IP dose #1 on 17 Aug 2020. Subject does not qualify to receive Dose 2; therefore, IP withdrawn" noted. However, this is not reflected in CCG page 38-39. Please review and ensure that the date of discontinuation reflects when the decision to discontinue the Treatment was established. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:31:12
User opened query 'Per DM CLR - RQ: Site's response "Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Subject received IP dose #1 on 17 Aug 2020. Subject does not qualify to receive Dose 2; therefore, IP withdrawn" noted. However, this is not reflected in CCG page 38-39. Please review and ensure that the date of discontinuation reflects when the decision to discontinue the Treatment was established. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 04:51:02
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 08:07:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'd/t covid 19 infection' (Site from System). User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	Lyly Dang (b) (4) (b) (4)	18 Nov 2020 18:34:54
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. ' (Site from DM).	System	18 Nov 2020 18:34:09
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. ' answered with 'Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure.	(b) (4), (b) (6) (b) (4)	02 Nov 2020 08:10:53
Subject received IP dose #1 on 17 Aug 2020. Subject does not qualify to receive Dose 2; therefore, IP withdrawn' (Site from DM).	Lyly Dang (b) (4) (b) (4)	01 Nov 2020 16:24:48
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:56:58
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		22 Oct 2020 22:33:52

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EAB) (1725)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	22 Oct 2020 22:33:52
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	22 Oct 2020 22:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User closed query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 17:48:27
Query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' answered with 'EDC updated.' (Site from Safety).	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:57:12
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:55:43
User opened query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 13:20:14
User closed query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' answered with 'SUBJECT CONTINUING IN TRIAL' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:27:39
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	09 Sep 2020 02:27:07
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	07 Sep 2020 19:42:37
User opened query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:19:19
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

None

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User closed query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' (Site from CRA).		06 Sep 2020 19:56:13
Query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' answered with 'No treatment was indicated to the subject for this event' (Site from CRA).	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:32:31
User opened query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 14:54:45
User entered 'I'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered '0'	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered '0'	Heather Cherniawski	01 Sep 2020 12:48:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved. Please keep query open until information is available.' canceled (Site from Safety).		08 Oct 2020 17:41:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	01 Oct 2020 16:25:02
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved. Please keep query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 10:53:40
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:44:43
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'WILL UPDATE WHEN AVAILABLE' (Site from Safety).	Karen Knapp (b) (4)	05 Sep 2020 21:37:34
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:18:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Heather Cherniawski	01 Sep 2020 12:48:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:09:25
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:09:25
Query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' canceled (Site from Safety).		14 Sep 2020 15:36:23
Query 'PV query: Please confirm if the vaccination was given on 17 Aug 2020 (as reported in EDC) or 27 Aug 2020 (as reported on SD).' canceled (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:36:18
User opened query 'PV query: Please confirm if the vaccination was given on 17 Aug 2020 (as reported in EDC) or 27 Aug 2020 (as reported on SD).' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 10:56:14
User opened query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 10:55:43
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:57
User closed query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:54
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:45
User closed query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:42
User closed query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:53:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 01:45:00
Query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' answered with 'NO KNOWN CONTACTS REPORTED. PER SUBJECT, SUBJECT IS A CAR SALESMAN AND LIVES IN HIGH DENSITY HOUSING. PRIOR TO ONSET OF SYMPTOMS, SUBJECT TOOK A TRIP TO LAS VEGAS.' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:51:37
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' answered with 'SUBJECT REPORTS NO CONCOMITANT MEDICATIONS TAKEN.' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:40:32
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' answered with 'ASSESSMENT TAB COMPLETED' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:38:07
Query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' answered with 'BASELINE TEST RESULT "NOT DETECTED". TEST PERFORMED 27 AUG 2020 RESULTED POSITIVE.' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:37:03
Query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' answered with 'NOT DETECTED RESULTED 22 AUG 2020' (Site from Safety).	Heather Cherniawski (b) (4)	09 Sep 2020 02:35:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'NO TREATMENT GIVEN' (Site from Safety).	Heather Cherniawski (b) (4)	08 Sep 2020 12:57:43
User entered 'Subject had a negative PCR swab at his day 1 visit on 17 Aug 2020. Subject reported COVID-19 related symptoms that started on Aug 24th. The subject experienced the following symptoms after returning from his recent Vegas trip: cough, fatigue, myalgia, headache, nasal congestion, and runny nose. The subject denies using any medications or undergoing any medical treatment for his symptoms. The subject returned to the clinic for an illness visit on 27 Aug 2020. The subject had a positive PCR swab at his day 1 illness visit. Currently the subject is asymptomatic.' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	08 Sep 2020 12:55:06
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 19:56:20
User opened query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:20:14
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:20:05
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:19:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:19:47
User opened query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:19:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 11:19:05
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 14:53:20
User entered empty.	Heather Cherniawski (b) (4)	01 Sep 2020 12:48:51

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Oct 2020 22:55:43
User entered '1'	System	11 Sep 2020 02:45:42
User entered '0'	System	01 Sep 2020 12:48:51

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 12:48:51

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:34:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:13:08
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
DataPoint Un-verified.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:31:32
Signature has been broken.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:31:32
User entered 'Yes (Y)' reason for change: New Information	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:31:32
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:57:21
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Aug 2020 18:22:34

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE ACETATE, PRODUCTSYNONYM: DEPOMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:44:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:44:39
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
Data point term sent to Coder	System	16 Apr 2021 16:32:40
User entered 'DepoMedrol'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Yes (Y)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Seasonal Allergies'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered '2'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'mL (mL)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered empty.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'once (ONCE)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered empty.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'Intramuscular (INTRAMUSCULAR)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered empty.	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered '16 Apr 2021'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered '0'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'No (N)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered '16 Apr 2021'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:06
User entered 'No (N)'	Maureen Dempsey (b) (4) (b) (4)	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:32:28

US3812197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:34:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:10:30
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	02 Sep 2020 20:19:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:19
User entered 'Visit 2 Day 29 (VISIT2)'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:21
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User closed query 'please only check boxes applicable to D29V2' (Site from CRA).		18 Nov 2020 20:30:34
Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:11:17
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:10:34
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:23
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:46:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:46:01
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:22
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:11:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:29
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:25
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query "? please only check boxes applicable to D29V2 ?	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:34:48
? please only check boxes applicable to D29V2 ?		
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query "? please only check boxes applicable to D29V2 ?	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:43
? please only check boxes applicable to D29V2 ?		
please only check boxes applicable to V2 ' answered with 'UPDATED' (Site from CRA).		
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query "? please only check boxes applicable to D29V2 ?	(b) (4), (b) (6)	16 Nov 2020 19:45:59
? please only check boxes applicable to D29V2 ?		
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:37
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:29
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query "? please only check boxes applicable to D29V2 ?	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:50
Cancel ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query "? please only check boxes applicable to D29V2 ?	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:47
Cancel ' answered with 'UPDATED' (Site from CRA). User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query "? please only check boxes applicable to D29V2 ?	(b) (4), (b) (6)	16 Nov 2020 19:45:27
Cancel ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:41
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:27
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:07:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:36
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please only check boxes applicable to D29V2 ?	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:34:54
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query 'please only check boxes applicable to D29V2 ?	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:51
please only check boxes applicable to V2 ' answered with 'UPDATED' (Site from CRA).		
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query 'please only check boxes applicable to D29V2 ?	(b) (4), (b) (6)	16 Nov 2020 19:46:22
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:07:56
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:35
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please only check boxes applicable to D29V2 ?	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:31:02
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query 'please only check boxes applicable to D29V2 ?	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:57
please only check boxes applicable to V2 ' answered with 'UPDATED' (Site from CRA).		
User opened query 'please only check boxes applicable to D29V2 ?	(b) (4), (b) (6)	16 Nov 2020 19:46:33
please only check boxes applicable to V2 ' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:38
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:40
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:42
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:43
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4)	18 Nov 2020 20:31:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4)	18 Nov 2020 18:19:01
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
User opened query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4)	16 Nov 2020 18:12:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:23
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:08:06
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:51
User entered '1'	Heather Cherniawski	23 Oct 2020 22:11:45
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:31:25
DataPoint Verified.		18 Nov 2020 20:30:39
Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:19:05
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:12:48
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:39
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:12:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:48
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:12
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:46
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:26:17
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:58:55
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please only check boxes applicable to D29V2' (Site from CRA).	(b) (4)	18 Nov 2020 20:31:34
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:19:10
User opened query 'please only check boxes applicable to D29V2' (Site from CRA).	Breanna Galibert (b) (4)	16 Nov 2020 18:13:21
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:13:15
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:29:28
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:28:43
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:56
User entered '0'	Heather Cherniawski	23 Oct 2020 22:11:45
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:58:58
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:00
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
User entered '1'	(b) (4) Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:19
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:26:22
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:14:06
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:04
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:02
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:39
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:06
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Nov 2020 18:18:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:08:35
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:09
User entered '1'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:08:32
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:11
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:14
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:16
User entered '21 Sep 2020'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:18
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

Study Treatment not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'please check as no IP given for V2' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:31:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
Query 'please check as no IP given for V2' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:19:17
User entered '1' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	18 Nov 2020 18:18:31
User opened query 'please check as no IP given for V2' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:30:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:59:20
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

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Generated On: 12 Aug 2021 13:34:50

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:25
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:28
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:30
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:32
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:34
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:36
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:39
User entered 'SUBJECT WAS IN CONVALESCENT PERIOD. VISIT 2 NOT DONE.'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

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[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:41
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:44
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:45
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:47
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:49
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:52
User entered 'I'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:54
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:56
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:59:59
User entered '0'	Heather Cherniawski (b) (4)	23 Oct 2020 22:11:45

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:10:22
User entered 'Visit 2 Day 29 (VISIT2)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:02
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:04
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:08
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:10
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:11
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:10:26
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:18
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:21
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:23
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:25
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:27
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:33
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:37
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:35
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:41
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:43
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:47
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

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[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:49
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:07:54
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:07:57
User entered '22 Sep 2020'	Breanna Galibert (b) (4)	31 Oct 2020 20:22:25
	(b) (4)	

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:08
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:09
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:11
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:14
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:17
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:22
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:20
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:25
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:27
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:30
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:32
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:34
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:36
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:38
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:44
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 12 Aug 2021 13:34:50

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:08:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:22:25

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:03
User entered 'Visit 2 Day 29 (VISIT2)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:01
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:05
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:21
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:23
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:28
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:40
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:12
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:10
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:09
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:07
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:03
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:05
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:57
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:54
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:48
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:50
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:12
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:13
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:19
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:11:18
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	31 Oct 2020 20:23:02
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:22
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:24
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:26
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:28
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:29
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:31
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:34
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:11:38
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:03
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:01
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:06
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:08
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:13
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:11
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:16
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:18
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 12 Aug 2021 13:34:50

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:12:51
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:02

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:29
User entered 'Visit 2 Day 29 (VISIT2)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:28
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:32
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:35
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:37
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:41
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:42
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:44
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:50
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:49
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:47
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:53
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:47:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:48:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:54
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:01
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:49:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:03
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:05
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:08
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:13
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:11
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:14
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:50:17
User entered '6 Oct 2020'	Breanna Galibert (b) (4)	31 Oct 2020 20:23:33
	(b) (4)	

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:18
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:20
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:22
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:24
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:26
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:30
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:32
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:28
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:33
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:36
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:41
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:43
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:48
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:50
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:52
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 12 Aug 2021 13:34:50

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:50:54
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:23:33

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:51:11
User entered 'Visit 3 Day 57 (VISIT3)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:51:13
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 19:51:49
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:51:15
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.		16 Nov 2020 19:51:51
DataPoint Verified.		16 Nov 2020 19:51:17
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.		16 Nov 2020 19:51:53
DataPoint Verified.		16 Nov 2020 19:51:19
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.		16 Nov 2020 19:51:57
DataPoint Verified.		16 Nov 2020 19:51:21
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.		16 Nov 2020 19:51:58
DataPoint Verified.		16 Nov 2020 19:51:22
User entered '0'	Breanna Galibert (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.		16 Nov 2020 19:52:00
DataPoint Verified.		16 Nov 2020 19:51:23
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:51:25
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 19:51:42
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 19:51:28
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:51:30
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:51:33
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:33:06
User opened query 'Date of Missed or Out of Window Visit or Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:30:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '20 Oct 2020'	Breanna Galibert (b) (4)	31 Oct 2020 20:24:21
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 12 Aug 2021 13:34:50

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:30:39
User entered '0'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 20:24:21

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per CDM: Per pages 46-47 of CCGs version 3.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 14:35:31
Query 'Per CDM: Per pages 46-47 of CCGs version 3.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' answered with 'CORRECTED ENTRY ERROR' (Site from DM).	Anya Penly (b) (4) (b) (4)	23 Dec 2020 17:48:10
User entered '17 Aug 2020' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	23 Dec 2020 17:47:55
User opened query 'Per CDM: Per pages 46-47 of CCGs version 3.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:03:32
Query 'Per CDM: Date of last exposure is "17 AUG 2020" during VID1. Date of dosing discontinuation is "27 AUG 2020". Per pages 46-47 of CCGs version 3.0 the two dates should be the same. Please review and reconcile. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:03:27

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM: Date of last exposure is "17 AUG 2020" during V1D1. Date of dosing discontinuation is "27 AUG 2020". Per pages 46-47 of CCGs version 3.0 the two dates should be the same. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:00:02
User entered '27 Aug 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Dec 2020 23:36:02
User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	16 Dec 2020 23:31:53
User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Dec 2020 23:31:45
User entered '28 Aug 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Dec 2020 23:31:45
User entered '17 Aug 2020'	(b) (4)	22 Oct 2020 22:23:43
	Lyly Dang (b) (4)	
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' (Site from DM). Query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:07:45
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Nov 2020 18:34:15
User opened query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' (Site from DM).	Lyly Dang (b) (4) (b) (4)	18 Nov 2020 18:34:09
User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 12:48:18
Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' answered with 'DUE TO SARS-COV-2' (Site from DM).	Heather Cherniawski (b) (4)	12 Nov 2020 20:40:13
User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:09:42
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	22 Oct 2020 22:33:52
User entered 'Due to SARS-COV-2 (COVID)'	Lyly Dang (b) (4) (b) (4)	22 Oct 2020 22:23:43

US3812197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:50

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 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Lyly Dang (b) (4)	18 Nov 2020 18:34:09
User entered 'Due to SARS-COV 2' reason for change: Data Entry Error	Lyly Dang (b) (4)	22 Oct 2020 22:33:52
User entered empty.	Lyly Dang (b) (4)	22 Oct 2020 22:23:43

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:11
Query 'Data is required. Please complete.' answered with 'NA' (Site from System).	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:33:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:33:06
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:33:06
User entered '28 Aug 2020' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:31:53
User entered '17 Aug 2020'	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:55:19
Query 'Data is required. Please complete.' answered with 'NA' (Site from System).	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:33:19
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:33:06
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:33:06
User entered 'AE (specify) (ADVERSE EVENT)'	Angie Kean (b) (4) (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

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 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	16 Dec 2020 23:33:06
User entered 'COVID-19 POSITIVE'	Angie Kean (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Angie Kean (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Angie Kean (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Angie Kean (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:50

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
User entered empty.	Angie Kean (b) (4)	16 Dec 2020 23:30:25

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '01/Sep/2020 14:28'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered '1'		01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:06
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:58:35
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:57:40
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:39
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '10/Sep/2020 10:08'	System	10 Sep 2020 14:08:22

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
User entered '1' reason for change: Data Entry Error		10 Sep 2020 14:08:22
User entered '0'		10 Sep 2020 14:07:19

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '12/Sep/2020 12:53'	System	12 Sep 2020 16:53:36

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
User entered 'I'		12 Sep 2020 16:53:36

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:06
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:58:35
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:57:40
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:39
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '15/Sep/2020 09:25'	System	15 Sep 2020 13:25:21

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:04:10
User entered '1'		15 Sep 2020 13:25:21

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '17/Sep/2020 11:04'	System	17 Sep 2020 15:04:27

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:26:35
User entered 'I'		17 Sep 2020 15:04:27

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:06
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:58:35
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:57:40
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:39
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:56:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '17/Sep/2020 11:26'	System	17 Sep 2020 15:26:43

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 00:38:23
User entered 'I'		17 Sep 2020 15:26:43

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '01/Oct/2020 20:38'	System	02 Oct 2020 00:38:37

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:50:02
User entered 'I'		02 Oct 2020 00:38:37

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	18 Oct 2020 22:59:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
User entered '19/Oct/2020 17:50'	System	19 Oct 2020 17:50:18

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:48
User entered 'I'		19 Oct 2020 17:50:18

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:31
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'USA-US111-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:28
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:58:35
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:58:35
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:57:40
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:57:40
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:39
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:39
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:56:29
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:56:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:32
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:35
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		19 Oct 2020 17:50:02
User entered 'No (N)'	System	18 Oct 2020 23:00:14
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:27
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:27
	(b) (4)	
User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
Un-reviewed for Safety.	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	18 Oct 2020 22:59:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered 'Yes (Y)'	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered 'No (N)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'lauren'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Larkin'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'clement'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'Wadsworth'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6) '	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '711 Old Ballas Rd Suite 105'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered 'St Louis'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered 'MO'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
Un-reviewed for Safety.	System	01 Apr 2021 20:13:08
DataPoint Un-verified.	System	01 Apr 2021 20:13:08
Signature has been broken.	System	01 Apr 2021 20:13:08
User entered empty.	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Reviewed for Safety.		15 Sep 2020 13:25:07
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 22:01:29
Amendment Manager: User entered '63141'	System	14 Sep 2020 22:01:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 16:53:21
Un-reviewed for Safety.	System	11 Sep 2020 02:48:32
User entered empty.	System	11 Sep 2020 02:48:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 18:28:46
User entered (b) (6)'	System	01 Sep 2020 18:27:10

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:56:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:40:25
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 14:07:08
User entered 'US' (non-conformant).	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:34:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	01 Apr 2021 20:13:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 20:04:59
	(b) (4)	
User entered '8'	System	19 Oct 2020 17:50:18
User entered '7'	System	02 Oct 2020 00:38:37
User entered '6'	System	17 Sep 2020 15:26:43
User entered '5'	System	17 Sep 2020 15:04:27
User entered '4'	System	15 Sep 2020 13:25:21
User entered '3'	System	12 Sep 2020 16:53:36
User entered '2'	System	10 Sep 2020 14:08:22
User entered '1'	System	01 Sep 2020 18:28:55

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 12 Aug 2021 13:34:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
User entered '01/Apr/2021 16:13'	System	01 Apr 2021 20:13:08

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 12 Aug 2021 13:34:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:54:15
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:38:43
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 20:13:08