

US3882049 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:45:16

All time stamps listed in this document are displayed in GMT

US3882049

Form: Participant Creation

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Participant ID

US3882049

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

US3882049

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

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

Visit date (dd MMM yyyy)	19 OCT 2020
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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	SCRN
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US3882049

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3882049

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3882049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Condition	PRE-DIABETES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3882049

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Condition	MALIGNANT MELANOMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3882049

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:30
Height (xxx.x)	72 in
Weight (xxx.x)	200 lb
BMI (xxx.x)	27.18159 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Oct 2020 23:21:26

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Dec 2020 22:12:52

Generated On: 12 Aug 2021 13:45:16

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

ADMINISTRATION

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) 12 Dec 2020 22:12:52

Generated On: 12 Aug 2021 13:45:16

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) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

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

Visit date (dd MMM yyyy)	23 OCT 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 191754

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) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Height	72 in
Weight	200 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Height	72 in
Weight	200 lb
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)	23 OCT 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:45
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	SURFACE
Pulse (xxx)	80 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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Height	72 in
Weight	200 lb
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)	23 OCT 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 15:09
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 14:39

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) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

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

Collection date (dd MMM yyyy)	23 OCT 2020
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Collection time (00:00-23:59)	14:00 (24 HR)
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Collection date and time (derived)	23 OCT 2020 14:00
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	23 OCT 2020 14:05
Nasopharyngeal Swab 2	No		

US3882049

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Oct 2020 14:32:36

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 15:07

PC Open Date & Time

23 OCT 2020 14:59

PC Close Date & Time

23 OCT 2020 17:29

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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 97.7 °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	23 OCT 2020 20:26
PC Open Date & Time	23 OCT 2020 18:24
PC Close Date & Time	24 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

24 OCT 2020 18:54

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

97.8 °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

25 OCT 2020 20:55

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 19:26

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 20:17

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

28 OCT 2020 21:00

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

96.7 °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

29 OCT 2020 21:39

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 15:03

PC Open Date & Time

23 OCT 2020 14:59

PC Close Date & Time

23 OCT 2020 17:29

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

23 OCT 2020 20:16

PC Open Date & Time

23 OCT 2020 18:24

PC Close Date & Time

24 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

24 OCT 2020 18:55

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

25 OCT 2020 20:55

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

26 OCT 2020 19:26

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

27 OCT 2020 20:18

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

28 OCT 2020 21:01

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

29 OCT 2020 21:40

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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 ☐

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 15:02
PC Open Date & Time	23 OCT 2020 14:59
PC Close Date & Time	23 OCT 2020 17:29

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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 ☐

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 20:16
PC Open Date & Time	23 OCT 2020 18:24
PC Close Date & Time	24 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 18:55
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 20:56
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:27
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

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 ☒

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 20:18
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

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 ☒

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 21:02
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

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 ☒

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EAB) (1725)

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 21:41
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3882049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 31 Oct 2020 01:33:51

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments DENIES FEVER, CHILLS,
COUGH, SORE THROAT,
If Contact Not Made, please provide Comments HEADACHE, MALAISE, N/V.

US3882049

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 31 Oct 2020 01:33:51

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 23:34:36

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 07 Nov 2020 16:24:27

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Nov 2020 00:52:57

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Nov 2020 00:52:57

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 20:14:05

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 19:47:20
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 11:58:16
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 JAN 2021 13:14:51
Patient Cloud Open Date & Time	10 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
76 of 4099	

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:36:05

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 07:32:48
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

02 FEB 2021 07:06:17

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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	08 FEB 2021 18:10:56
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

16 FEB 2021 18:35:21

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 21:26:51

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

28 FEB 2021 23:03:42

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

07 MAR 2021 09:50:05

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 <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 MAR 2021 07:05:55
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 10:09:36
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

28 MAR 2021 10:06:13

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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	04 APR 2021 09:12:27
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

12 APR 2021 12:03:52

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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	19 APR 2021 18:05:49
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 <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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 <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 MAY 2021 21:09:49
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

13 MAY 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

20 MAY 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

27 MAY 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 MAY 2021 00:01

Patient Cloud Close Date & Time

03 JUN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 JUN 2021 00:01

Patient Cloud Close Date & Time

10 JUN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 JUN 2021 00:01

Patient Cloud Close Date & Time

17 JUN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

24 JUN 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 JUN 2021 00:01

Patient Cloud Close Date & Time

01 JUL 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 <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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

08 JUL 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

15 JUL 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 JUL 2021 00:01

Patient Cloud Close Date & Time

22 JUL 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 JUL 2021 00:01

Patient Cloud Close Date & Time

29 JUL 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

05 AUG 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 AUG 2021 00:01

Patient Cloud Close Date & Time

12 AUG 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

19 AUG 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 AUG 2021 00:01

Patient Cloud Close Date & Time

26 AUG 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 AUG 2021 00:01

Patient Cloud Close Date & Time

02 SEP 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 SEP 2021 00:01

Patient Cloud Close Date & Time

09 SEP 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

16 SEP 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

23 SEP 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 SEP 2021 00:01

Patient Cloud Close Date & Time

30 SEP 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

07 OCT 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 OCT 2021 00:01

Patient Cloud Close Date & Time

14 OCT 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

21 OCT 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2021 00:01

Patient Cloud Close Date & Time

28 OCT 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2021 00:01

Patient Cloud Close Date & Time

04 NOV 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2021 00:01

Patient Cloud Close Date & Time

11 NOV 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

18 NOV 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

25 NOV 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 NOV 2021 00:01

Patient Cloud Close Date & Time

02 DEC 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

09 DEC 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

16 DEC 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 DEC 2021 00:01

Patient Cloud Close Date & Time

23 DEC 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 DEC 2021 00:01

Patient Cloud Close Date & Time

30 DEC 2021 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

06 JAN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

13 JAN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

20 JAN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JAN 2022 00:01

Patient Cloud Close Date & Time

27 JAN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

03 FEB 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

10 FEB 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

17 FEB 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 FEB 2022 00:01

Patient Cloud Close Date & Time

24 FEB 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 FEB 2022 00:01

Patient Cloud Close Date & Time

03 MAR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

10 MAR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 MAR 2022 00:01

Patient Cloud Close Date & Time

17 MAR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 MAR 2022 00:01

Patient Cloud Close Date & Time

24 MAR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

31 MAR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 APR 2022 00:01

Patient Cloud Close Date & Time

07 APR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

14 APR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 APR 2022 00:01

Patient Cloud Close Date & Time

21 APR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 APR 2022 00:01

Patient Cloud Close Date & Time

28 APR 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

05 MAY 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 MAY 2022 00:01

Patient Cloud Close Date & Time

12 MAY 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 MAY 2022 00:01

Patient Cloud Close Date & Time

19 MAY 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

26 MAY 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

02 JUN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

09 JUN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 JUN 2022 00:01

Patient Cloud Close Date & Time

16 JUN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 JUN 2022 00:01

Patient Cloud Close Date & Time

23 JUN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 JUN 2022 00:01

Patient Cloud Close Date & Time

30 JUN 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUL 2022 00:01

Patient Cloud Close Date & Time

07 JUL 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 JUL 2022 00:01

Patient Cloud Close Date & Time

14 JUL 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

21 JUL 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 JUL 2022 00:01

Patient Cloud Close Date & Time

28 JUL 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 JUL 2022 00:01

Patient Cloud Close Date & Time

04 AUG 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 AUG 2022 00:01

Patient Cloud Close Date & Time

11 AUG 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

18 AUG 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 AUG 2022 00:01

Patient Cloud Close Date & Time

25 AUG 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 AUG 2022 00:01

Patient Cloud Close Date & Time

01 SEP 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 SEP 2022 00:01

Patient Cloud Close Date & Time

08 SEP 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 SEP 2022 00:01

Patient Cloud Close Date & Time

15 SEP 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

22 SEP 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

29 SEP 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

06 OCT 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

13 OCT 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

20 OCT 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 OCT 2022 00:01

Patient Cloud Close Date & Time

27 OCT 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 OCT 2022 00:01

Patient Cloud Close Date & Time

03 NOV 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

10 NOV 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

17 NOV 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

24 NOV 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

01 DEC 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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="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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

08 DEC 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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°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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

Patient Cloud Close Date & Time

15 DEC 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 DEC 2022 00:01

Patient Cloud Close Date & Time

22 DEC 2022 23:59

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 DEC 2022 00:01

Patient Cloud Close Date & Time

29 DEC 2022 23:59

US3882049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:45:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:04:05

US3882049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 27 Mar 2021 15:10:30

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 04:29:09

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 27 Mar 2021 15:10:30

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 FEB 2021

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

Comments NO ANSWER, LEFT VOICEMAIL.
SECOND ATTEMPT 2/25 AND
CONTACT MADE.
If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 04:29:09

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 27 Mar 2021 15:10:30

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 27 Mar 2021 15:10:30

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:53:21

Generated On: 12 Aug 2021 13:45:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

DENIES SYMPTOMS. DENIES
CHANGES IN HEALTH HISTORY
OR MEDICATION LIST.

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:53:21

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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 _____

US3882049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

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.

US3882049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

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

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

US3882049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 25 Feb 2021 04:29:09

Generated On: 12 Aug 2021 13:45:16

Date of Contact	22 NOV 2020
Time of Contact	17:00
Date and Time of Contact (derived)	22 NOV 2020 17:00
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>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

Symptom Day

Day 1	<input checked="" 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 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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	103 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 type="radio"/>
	Moderate <input checked="" 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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US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	100.8 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 type="radio"/>
	Moderate	<input checked="" 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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US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	100.5 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 type="radio"/>
	Moderate	<input checked="" 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 22 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	98.8 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 22 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	98.2 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 22 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 NOV 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.4 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 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 22 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.3 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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EAB) (1725)

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 DEC 2020
------	-------------

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

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

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

Temperature	98.4 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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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 22 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.5 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 22 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

	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 22 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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"/>

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Dec 2020 22:12:52

Generated On: 12 Aug 2021 13:45:16

Date of Visit	25 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	25 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 20:12:54

Generated On: 12 Aug 2021 13:45:16

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 _____

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 20:12:54

Generated On: 12 Aug 2021 13:45:16

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 22 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 21 Feb 2021 20:12:54

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Mar 2021 23:24:25

Generated On: 12 Aug 2021 13:45:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 DEC 2020
Day 5	Yes	4 DEC 2020
Day 7	Yes	4 DEC 2020
Day 9	Yes	04 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	Yes	21 DEC 2020

US3882049

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Nov 2020 19:00:35

Generated On: 12 Aug 2021 13:45:16

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

Visit date (dd MMM yyyy)	25 NOV 2020
--------------------------	-------------

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

Folder OID	SICKD1
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US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Dec 2020 01:56:17

Generated On: 12 Aug 2021 13:45:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 16:15
Height (xxx.x)	72 in
Weight (xxx.x)	194 lb
Temperature (xxx.x)	103 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882049

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Nov 2020 19:00:35

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3882049

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Nov 2020 19:00:35

Generated On: 12 Aug 2021 13:45:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 NOV 2020

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 DEC 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 11:28
Height (xxx.x)	72 in
Weight (xxx.x)	194 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 DEC 2020

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

US3882049

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 DEC 2020

US3882049

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

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

Visit date (dd MMM yyyy)	6 JAN 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3882049

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 13:03:02

Generated On: 12 Aug 2021 13:45:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	6 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>)	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3882049

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3882049

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 10:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3882049

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 11:55
Temperature (xxx.x)	97.2 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3882049

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

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

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

US3882049

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

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

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) 6 JAN 2021

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 11:25

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

US3882049

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	10:48 (24 HR)
Collection date and time (derived)	6 JAN 2021 10:48

US3882049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	10:45
Collection Date and Time (derived)	6 JAN 2021 10:45

US3882049

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

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

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 + PAIN AT INJECTION SITE,
CHILLS, AND FEVER AT 103 F

If Contact Not Made, please provide Comments

US3882049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 03:25:40

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:46 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 11:46
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882049

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

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

US3882049

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

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

Collection date (dd MMM yyyy)	3 FEB 2021
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Collection time (00:00-23:59)	12:03 (24 HR)
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Collection date and time (derived)	3 FEB 2021 12:03
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US3882049

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Nov 2020 19:00:34

Generated On: 12 Aug 2021 13:45:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 16:08:40

Generated On: 12 Aug 2021 13:45:16

AEID	USA-US095-2020-MRNA-1273-P30 1000001
Adverse event	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)	25 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 16:08:40

Generated On: 12 Aug 2021 13:45:16

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	SUBJECT PRESENTED TO ED FOR COVID TEST. TEST WAS POSITIVE AND STUDY TEAM INITIATED ILLNESS VISIT.
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)	

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:08:40

Generated On: 12 Aug 2021 13:45:16

AEID

Adverse event

SPRAINED ANKLE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 16:08:40

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

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

Yes ☒

No ☐

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

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Oct 2020 01:34:35

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 20:12:54

Generated On: 12 Aug 2021 13:45:16

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3882049

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 26 Nov 2020 19:00:34

Generated On: 12 Aug 2021 13:45:16

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input 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	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
Dosing Discontinuation	

US3882049

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 26 Nov 2020 19:00:34

Generated On: 12 Aug 2021 13:45:16

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

US3882049

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Dec 2020 22:12:52

Generated On: 12 Aug 2021 13:45:16

Date of dosing discontinuation (dd MMM yyyy) 25 NOV 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

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 25 Dec 2020 22:22:52

Generated On: 12 Aug 2021 13:45:16

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 ☐

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

SAEID	USA-US095-2020-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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	11301 WILSHIRE BLVD
Site Address: City	LOS ANGELES
Site Address: State	CA
Site Address: Postal Code	90073
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

SAEID	USA-US095-2020-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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	11301 WILSHIRE BLVD
Site Address: City	LOS ANGELES
Site Address: State	CA
Site Address: Postal Code	90073
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/DEC/2020 14:01
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

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

SAEID	USA-US095-2020-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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	11301 WILSHIRE BLVD
Site Address: City	LOS ANGELES
Site Address: State	CA
Site Address: Postal Code	90073
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/DEC/2020 17:29
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

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

SAEID	USA-US095-2020-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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	11301 WILSHIRE BLVD
Site Address: City	LOS ANGELES
Site Address: State	CA
Site Address: Postal Code	90073
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/DEC/2020 16:24
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

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 20:13:15

Generated On: 12 Aug 2021 13:45:16

SAEID	USA-US095-2020-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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	11301 WILSHIRE BLVD
Site Address: City	LOS ANGELES
Site Address: State	CA
Site Address: Postal Code	90073
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/JAN/2021 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

Audit

US3882049 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

US3882049

Form: Participant Creation

Generated On: 12 Aug 2021 13:45:16

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 05:55:38
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'US3882049'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 19:28:46

US3882049

Form: Participant Creation

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:30:33
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:24:16

US3882049

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:30:33
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '19 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 19:28:47

US3882049

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:30:33
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Clinic (Clinic)'	Sara Wong (b) (4)	19 Oct 2020 21:24:16
	(b) (4)	

US3882049

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'SCRN'	System	19 Oct 2020 21:24:16

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 19:28:48

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '66'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'YEARS'	System	19 Oct 2020 21:28:52

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '66'	System	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) recorded on this form does not match with Sex (female) recorded in PPD Central lab. Please reconcile the data and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:16:32
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) recorded on this form does not match with Sex (female) recorded in PPD Central lab. Please reconcile the data and update as appropriate. ' answered with 'A request has been submitted to update the records. This subject is MALE' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	10 Nov 2020 18:07:18
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Sex (male) recorded on this form does not match with Sex (female) recorded in PPD Central lab. Please reconcile the data and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:14:55
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Male (M)'	Sara Wong (b) (4) (b) (4)	19 Oct 2020 21:28:52

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'I'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:45:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:31:45
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:28:52
	(b) (4)	

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '19 Oct 2020'	Sara Wong (b) (4)	19 Oct 2020 21:29:05
	(b) (4)	

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'Oct 2020'	System	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '2020'	System	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Amendment 4 (4)'	Sara Wong (b) (4)	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	Sara Wong (b) (4)	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	Sara Wong (b) (4)	19 Oct 2020 21:29:05
	(b) (4)	

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:29:05

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:32:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Oct 2020 19:28:47

US3882049

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:45:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '1'	System	19 Oct 2020 21:29:31

US3882049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 05:55:25
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:29:31
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:45:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:41:37
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
Signature has been broken.	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:39
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:29:38

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:38:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:38:37
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 23:37:36
User entered 'Hyperlipidemia'	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'I'	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '0'	Suchi Tiwari (b) (4)	27 Oct 2020 23:36:56
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:36:56

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:36:56

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:36:56

US3882049

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:36:56

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:38:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:38:37
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 23:37:36
User entered 'Pre-diabetes'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'I'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '0'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:17
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:17

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:17

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:17

US3882049

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:17

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Malignant melanoma - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:39:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:39:37
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 23:38:36
User entered 'Malignant melanoma'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'I'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '0'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:36
	(b) (4)	

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:36

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:36

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:36

US3882049

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Oct 2020 23:37:36

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '19 Oct 2020'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '11:30'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '19 Oct 2020 11:30'	System	19 Oct 2020 21:31:40

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '72' in	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	
DataPoint set to visible.	System	19 Oct 2020 21:29:31

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '200' lb	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	
DataPoint set to visible.	System	19 Oct 2020 21:29:31

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '27.18159'	System	19 Oct 2020 21:31:40
DataPoint set to visible.	System	19 Oct 2020 21:29:31

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'kg/m2'	System	19 Oct 2020 21:31:40
DataPoint set to visible.	System	19 Oct 2020 21:29:31

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '97.7' F	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Oral (Oral)'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '68'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'bpm'	System	19 Oct 2020 21:31:40

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '15'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'breaths/min'	System	19 Oct 2020 21:31:40

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '139'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	19 Oct 2020 21:31:40

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '80'	Sara Wong (b) (4)	19 Oct 2020 21:31:40
	(b) (4)	

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	19 Oct 2020 21:31:40

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19

US3882049

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19

US3882049

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:31:46
	(b) (4)	

US3882049

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '19 Oct 2020'	Sara Wong (b) (4)	19 Oct 2020 21:31:46
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:40
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:39
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:37
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:34
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:32
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:31
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:28
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:26
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:25
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:23
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:20
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'No (N)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:18
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Yes (Y)'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:17
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered 'Administration'	Sara Wong (b) (4)	19 Oct 2020 21:32:15

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:16
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:12
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 02:44:18
User closed query 'Source shows this risk as checked. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 02:44:10
Query 'Source shows this risk as checked. Please reconcile. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	02 Dec 2020 16:17:40
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 16:17:35
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 16:17:35
	(b) (4)	
User opened query 'Source shows this risk as checked. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 06:34:59
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:10
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 02:44:22
User closed query 'Source does not show this risk as checked. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 02:44:20
Query 'Source does not show this risk as checked. Please reconcile. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	02 Dec 2020 16:17:45
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 16:17:35
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 16:17:35
	(b) (4)	
User opened query 'Source does not show this risk as checked. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 06:34:13
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '1'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered '0'	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:45:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:35:08
User signature succeeded.	Michael Lewis (b) (4)	19 Oct 2020 23:21:27
User entered empty.	Sara Wong (b) (4)	19 Oct 2020 21:32:15
	(b) (4)	

US3882049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:40:40
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:43:34

US3882049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:40:40
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 Oct 2020'	Sara Wong (b) (4)	23 Oct 2020 21:43:34

US3882049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:40:40
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Clinic (Clinic)'	Sara Wong (b) (4)	23 Oct 2020 21:43:34

US3882049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'VISIT1'	System	23 Oct 2020 21:43:34

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 20:53:27

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '191754'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 20:53:27

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 20:53:27

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57

US3882049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:41:31
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:43:57
DataPoint set to visible.	(b) (4) System	19 Oct 2020 21:29:05

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '72' in	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '200' lb	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '72' in	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '200' lb	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User accepted default value 'Pre-Dose (PREDOSE)'	Sara Wong (b) (4) (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '23 Oct 2020'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '13:45'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '23 Oct 2020 13:45'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '98' F	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Other (Other)'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Surface'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '80'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'bpm'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '16'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'breaths/min'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '122'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'mmHg'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '74'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'mmHg'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '72' in	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '200' lb	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User accepted default value 'Post-Dose (POSTDOSE)'	Sara Wong (b) (4) (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '23 Oct 2020'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '15:09'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '23 Oct 2020 15:09'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '98.1' F	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Oral (Oral)'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '72'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'bpm'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '16'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'breaths/min'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '128'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'mmHg'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '84'	Sara Wong (b) (4)	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'mmHg'	System	26 Oct 2020 18:24:51

US3882049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:46:57

US3882049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 Oct 2020'	Sara Wong (b) (4)	23 Oct 2020 21:46:57

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered empty.	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered empty.	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 Oct 2020'	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '14:39'	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '23 Oct 2020 14:39'	System	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Left Arm (LEFT ARM)'	Sara Wong (b) (4)	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'ONCE'	System	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 21:45:33

US3882049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:46:27

US3882049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 Oct 2020'	Sara Wong (b) (4)	23 Oct 2020 21:46:27

US3882049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '14:00'	Sara Wong (b) (4)	23 Oct 2020 21:46:27

US3882049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '23 Oct 2020 14:00'	System	23 Oct 2020 21:46:27

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:45:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '23 Oct 2020'	Sara Wong (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:45:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sara Wong (b) (4) (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:45:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered '14:05'	Sara Wong (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '23 Oct 2020 14:05'	System	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:45:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sara Wong (b) (4) (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'No (N)'	Sara Wong (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:45:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered empty.	Sara Wong (b) (4)	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered empty.	System	23 Oct 2020 21:46:45

US3882049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Oct 2020 14:32:36
User entered 'Yes (Y)'	Sara Wong (b) (4)	23 Oct 2020 21:46:49

US3882049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '1'	System	23 Oct 2020 21:46:49

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:05:53', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3c5b1239-b94b-45c1-9310-3500837540a8' User entered 'Yes (Y)'	System	23 Oct 2020 22:07:49
	System	23 Oct 2020 22:07:49

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:07:37', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3c5b1239-b94b-45c1-9310-3500837540a8' User entered '98.1'	System	23 Oct 2020 22:07:49
	System	23 Oct 2020 22:07:49

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:07:43', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3c5b1239-b94b-45c1-9310-3500837540a8'	System	23 Oct 2020 22:07:49
User entered 'No (N)'	System	23 Oct 2020 22:07:49

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:07:46', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3c5b1239-b94b-45c1-9310-3500837540a8' User entered '23 Oct 2020 15:07'	System	23 Oct 2020 22:07:49
	System	23 Oct 2020 22:07:49

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 14:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 17:29'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:25:36', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '84924306-d2ee-4e14-ace1-5464f32e1549' User entered 'Yes (Y)'	System	24 Oct 2020 03:26:09
	System	24 Oct 2020 03:26:09

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:25:48', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '84924306-d2ee-4e14-ace1-5464f32e1549' User entered '97.7'	System	24 Oct 2020 03:26:09
	System	24 Oct 2020 03:26:09

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:25:54', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '84924306-d2ee-4e14-ace1-5464f32e1549' User entered 'No (N)'	System	24 Oct 2020 03:26:09
	System	24 Oct 2020 03:26:09

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:26:04', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '84924306-d2ee-4e14-ace1-5464f32e1549' User entered '23 Oct 2020 20:26'	System	24 Oct 2020 03:26:09
	System	24 Oct 2020 03:26:09

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 18:24'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 2'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:53:52', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b03e84a7-c236-442a-80f0-324b9c01cfa1' User entered 'Yes (Y)'	System	25 Oct 2020 01:54:20
	System	25 Oct 2020 01:54:20

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:01', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b03e84a7-c236-442a-80f0-324b9c01cfa1' User entered '98.6'	System	25 Oct 2020 01:54:20
	System	25 Oct 2020 01:54:20

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:09', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b03e84a7-c236-442a-80f0-324b9c01cfa1' User entered 'No (N)'	System	25 Oct 2020 01:54:20
	System	25 Oct 2020 01:54:20

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:18', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b03e84a7-c236-442a-80f0-324b9c01cfa1' User entered '24 Oct 2020 18:54'	System	25 Oct 2020 01:54:20
	System	25 Oct 2020 01:54:20

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 3'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:54:55', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a50b5d8-3393-43d9-8c1c-e3b05b4e483e' User entered 'Yes (Y)'	System	26 Oct 2020 03:55:22
	System	26 Oct 2020 03:55:22

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:06', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a50b5d8-3393-43d9-8c1c-e3b05b4e483e' User entered '97.8'	System	26 Oct 2020 03:55:22
	System	26 Oct 2020 03:55:22

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:16', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a50b5d8-3393-43d9-8c1c-e3b05b4e483e' User entered 'No (N)'	System	26 Oct 2020 03:55:22
	System	26 Oct 2020 03:55:22

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:21', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a50b5d8-3393-43d9-8c1c-e3b05b4e483e' User entered '25 Oct 2020 20:55'	System	26 Oct 2020 03:55:22
	System	26 Oct 2020 03:55:22

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 4'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:10', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '708ebe8a-459b-4235-a5b2-687c83448d47'	System	27 Oct 2020 02:26:34
User entered 'Yes (Y)'	System	27 Oct 2020 02:26:34

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:19', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '708ebe8a-459b-4235-a5b2-687c83448d47' User entered '97.4'	System	27 Oct 2020 02:26:34
	System	27 Oct 2020 02:26:34

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:25', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '708ebe8a-459b-4235-a5b2-687c83448d47'	System	27 Oct 2020 02:26:34
User entered 'No (N)'	System	27 Oct 2020 02:26:34

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:28', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '708ebe8a-459b-4235-a5b2-687c83448d47'	System	27 Oct 2020 02:26:34
User entered '26 Oct 2020 19:26'	System	27 Oct 2020 02:26:34

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 5'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:16:43', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f52af80a-1d08-4967-a04e-4d9411acd23b' User entered 'Yes (Y)'	System	28 Oct 2020 03:17:45
	System	28 Oct 2020 03:17:45

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:16:49', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f52af80a-1d08-4967-a04e-4d9411acd23b' User entered '97.5'	System	28 Oct 2020 03:17:45
	System	28 Oct 2020 03:17:45

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:16:55', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f52af80a-1d08-4967-a04e-4d9411acd23b' User entered 'No (N)'	System	28 Oct 2020 03:17:45
	System	28 Oct 2020 03:17:45

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:17:42', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f52af80a-1d08-4967-a04e-4d9411acd23b' User entered '27 Oct 2020 20:17'	System	28 Oct 2020 03:17:45
	System	28 Oct 2020 03:17:45

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 6'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:00:34', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2e7e278e-faa8-4bd4-bcee-78566f0842b4' User entered 'Yes (Y)'	System	29 Oct 2020 04:01:00
	System	29 Oct 2020 04:01:00

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:00:44', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2e7e278e-faa8-4bd4-bcee-78566f0842b4' User entered '97.8'	System	29 Oct 2020 04:01:00
	System	29 Oct 2020 04:01:00

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:00:50', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2e7e278e-faa8-4bd4-bcee-78566f0842b4' User entered 'No (N)'	System	29 Oct 2020 04:01:00
	System	29 Oct 2020 04:01:00

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:00:56', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2e7e278e-faa8-4bd4-bcee-78566f0842b4' User entered '28 Oct 2020 21:00'	System	29 Oct 2020 04:01:00
	System	29 Oct 2020 04:01:00

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 7'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:39:29', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6fbdb8-1062-471b-aed3-6aa82623d30f' User entered 'Yes (Y)'	System	30 Oct 2020 04:40:03
	System	30 Oct 2020 04:40:03

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:39:40', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6fbdb8-1062-471b-aed3-6aa82623d30f' User entered '96.7'	System	30 Oct 2020 04:40:03
	System	30 Oct 2020 04:40:03

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:39:47', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6fbdb8-1062-471b-aed3-6aa82623d30f' User entered 'No (N)'	System	30 Oct 2020 04:40:03
	System	30 Oct 2020 04:40:03

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:39:57', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6fbdb8-1062-471b-aed3-6aa82623d30f' User entered '29 Oct 2020 21:39'	System	30 Oct 2020 04:40:03
	System	30 Oct 2020 04:40:03

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:48', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b777ea58-7b27-4892-9c85-0f72272a0b40' User entered 'None (1)'	System	23 Oct 2020 22:03:22
	System	23 Oct 2020 22:03:22

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:03:02', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b777ea58-7b27-4892-9c85-0f72272a0b40' User entered 'No (N)'	System	23 Oct 2020 22:03:22
	System	23 Oct 2020 22:03:22

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:03:07', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b777ea58-7b27-4892-9c85-0f72272a0b40' User entered 'No (N)'	System	23 Oct 2020 22:03:22
	System	23 Oct 2020 22:03:22

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:03:12', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b777ea58-7b27-4892-9c85-0f72272a0b40' User entered 'None (1)'	System	23 Oct 2020 22:03:22
	System	23 Oct 2020 22:03:22

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:03:17', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'b777ea58-7b27-4892-9c85-0f72272a0b40' User entered '23 Oct 2020 15:03'	System	23 Oct 2020 22:03:22
	System	23 Oct 2020 22:03:22

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 14:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 17:29'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:19', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3f5375fb-30f6-47b5-8c4e-16af9fdacbdb' User entered 'None (1)'	System	24 Oct 2020 03:16:55
	System	24 Oct 2020 03:16:55

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:25', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3f5375fb-30f6-47b5-8c4e-16af9fdacbdb' User entered 'No (N)'	System	24 Oct 2020 03:16:55
	System	24 Oct 2020 03:16:55

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:37', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3f5375fb-30f6-47b5-8c4e-16af9fdacbdb' User entered 'No (N)'	System	24 Oct 2020 03:16:55
	System	24 Oct 2020 03:16:55

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:44', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3f5375fb-30f6-47b5-8c4e-16af9fdacbdb' User entered 'None (1)'	System	24 Oct 2020 03:16:55
	System	24 Oct 2020 03:16:55

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:52', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '3f5375fb-30f6-47b5-8c4e-16af9fdacbdb' User entered '23 Oct 2020 20:16'	System	24 Oct 2020 03:16:55
	System	24 Oct 2020 03:16:55

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 18:24'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 2'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:32', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9f80c700-1436-45e3-a25d-aea970685169'	System	25 Oct 2020 01:55:12
User entered 'None (1)'	System	25 Oct 2020 01:55:12

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:42', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9f80c700-1436-45e3-a25d-aea970685169' User entered 'No (N)'	System	25 Oct 2020 01:55:12
	System	25 Oct 2020 01:55:12

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:54:53', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9f80c700-1436-45e3-a25d-aea970685169' User entered 'No (N)'	System	25 Oct 2020 01:55:12
	System	25 Oct 2020 01:55:12

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:06', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9f80c700-1436-45e3-a25d-aea970685169'	System	25 Oct 2020 01:55:12
User entered 'None (1)'	System	25 Oct 2020 01:55:12

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:09', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9f80c700-1436-45e3-a25d-aea970685169' User entered '24 Oct 2020 18:55'	System	25 Oct 2020 01:55:12
	System	25 Oct 2020 01:55:12

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 3'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:29', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '49566872-5969-45a1-b54d-20a784d61f13'	System	26 Oct 2020 03:55:44
User entered 'None (1)'	System	26 Oct 2020 03:55:44

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:32', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '49566872-5969-45a1-b54d-20a784d61f13'	System	26 Oct 2020 03:55:44
User entered 'No (N)'	System	26 Oct 2020 03:55:44

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:35', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '49566872-5969-45a1-b54d-20a784d61f13' User entered 'No (N)'	System	26 Oct 2020 03:55:44
	System	26 Oct 2020 03:55:44

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:38', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '49566872-5969-45a1-b54d-20a784d61f13'	System	26 Oct 2020 03:55:44
User entered 'None (1)'	System	26 Oct 2020 03:55:44

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:41', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '49566872-5969-45a1-b54d-20a784d61f13' User entered '25 Oct 2020 20:55'	System	26 Oct 2020 03:55:44
	System	26 Oct 2020 03:55:44

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 4'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:35', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '007cea1a-4733-4b7a-a357-8824f163b04e' User entered 'None (1)'	System	27 Oct 2020 02:26:58
	System	27 Oct 2020 02:26:58

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:40', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '007cea1a-4733-4b7a-a357-8824f163b04e' User entered 'No (N)'	System	27 Oct 2020 02:26:58
	System	27 Oct 2020 02:26:58

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:43', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '007cea1a-4733-4b7a-a357-8824f163b04e' User entered 'No (N)'	System	27 Oct 2020 02:26:58
	System	27 Oct 2020 02:26:58

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:47', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '007cea1a-4733-4b7a-a357-8824f163b04e' User entered 'None (1)'	System	27 Oct 2020 02:26:58
	System	27 Oct 2020 02:26:58

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:26:53', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '007cea1a-4733-4b7a-a357-8824f163b04e' User entered '26 Oct 2020 19:26'	System	27 Oct 2020 02:26:58
	System	27 Oct 2020 02:26:58

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 5'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:17:52', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f13559f9-26f8-4cf9-b2c7-569f97c3d83c'	System	28 Oct 2020 03:18:11
User entered 'None (1)'	System	28 Oct 2020 03:18:11

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:17:58', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f13559f9-26f8-4cf9-b2c7-569f97c3d83c' User entered 'No (N)'	System	28 Oct 2020 03:18:11
	System	28 Oct 2020 03:18:11

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:01', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f13559f9-26f8-4cf9-b2c7-569f97c3d83c' User entered 'No (N)'	System	28 Oct 2020 03:18:11
	System	28 Oct 2020 03:18:11

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f13559f9-26f8-4cf9-b2c7-569f97c3d83c'	System	28 Oct 2020 03:18:11
User entered 'None (1)'	System	28 Oct 2020 03:18:11

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:08', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'f13559f9-26f8-4cf9-b2c7-569f97c3d83c' User entered '27 Oct 2020 20:18'	System	28 Oct 2020 03:18:11
	System	28 Oct 2020 03:18:11

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 6'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:10', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '915c4be6-8b77-4819-8ba7-ccc5560e2d71' User entered 'None (1)'	System	29 Oct 2020 04:01:35
	System	29 Oct 2020 04:01:35

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:15', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '915c4be6-8b77-4819-8ba7-ccc5560e2d71' User entered 'No (N)'	System	29 Oct 2020 04:01:35
	System	29 Oct 2020 04:01:35

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:20', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '915c4be6-8b77-4819-8ba7-ccc5560e2d71' User entered 'No (N)'	System	29 Oct 2020 04:01:35
	System	29 Oct 2020 04:01:35

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:24', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '915c4be6-8b77-4819-8ba7-ccc5560e2d71' User entered 'None (1)'	System	29 Oct 2020 04:01:35
	System	29 Oct 2020 04:01:35

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:31', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '915c4be6-8b77-4819-8ba7-ccc5560e2d71' User entered '28 Oct 2020 21:01'	System	29 Oct 2020 04:01:35
	System	29 Oct 2020 04:01:35

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 7'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:03', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e2c59ab5-83d8-4798-9717-018ddca49cd2'	System	30 Oct 2020 04:40:48
User entered 'None (1)'	System	30 Oct 2020 04:40:48

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:24', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e2c59ab5-83d8-4798-9717-018ddca49cd2' User entered 'No (N)'	System	30 Oct 2020 04:40:48
	System	30 Oct 2020 04:40:48

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:28', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e2c59ab5-83d8-4798-9717-018ddca49cd2'	System	30 Oct 2020 04:40:48
User entered 'No (N)'	System	30 Oct 2020 04:40:48

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:32', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e2c59ab5-83d8-4798-9717-018ddca49cd2'	System	30 Oct 2020 04:40:48
User entered 'None (1)'	System	30 Oct 2020 04:40:48

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:46', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e2c59ab5-83d8-4798-9717-018ddca49cd2' User entered '29 Oct 2020 21:40'	System	30 Oct 2020 04:40:48
	System	30 Oct 2020 04:40:48

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:01:57', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:09', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:13', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:18', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:22', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:26', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'None (0)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:33', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered 'No (N)'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T15:02:38', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ffffe8a9-e385-4ccd-bcfe-5ff9670bc48b' User entered '23 Oct 2020 15:02'	System	23 Oct 2020 22:02:42
	System	23 Oct 2020 22:02:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 14:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 17:29'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:16', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:21', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:29', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:35', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:42', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8' User entered 'None (0)'	System	24 Oct 2020 03:16:10
	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:15:51', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8'	System	24 Oct 2020 03:16:10
User entered 'No (N)'	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-23T20:16:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '8ffe8d60-6a06-4a63-9963-0734c2fa9da8'	System	24 Oct 2020 03:16:10
User entered '23 Oct 2020 20:16'	System	24 Oct 2020 03:16:10

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '23 Oct 2020 18:24'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 2'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:15', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:18', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:21', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:27', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:30', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:33', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'None (0)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:36', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered 'No (N)'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-24T18:55:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7cd03895-b0f8-43f6-a7e6-b82562a93f09' User entered '24 Oct 2020 18:55'	System	25 Oct 2020 01:55:42
	System	25 Oct 2020 01:55:42

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 3'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:47', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:50', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:56', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:55:59', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:56:02', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:56:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'None (0)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:56:11', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered 'No (N)'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-25T20:56:15', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2cb334a7-43c3-40c6-a0a1-1ee720e98ffb' User entered '25 Oct 2020 20:56'	System	26 Oct 2020 03:56:17
	System	26 Oct 2020 03:56:17

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 4'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:01', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:04', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:08', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:11', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:14', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:16', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'None (0)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:24', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered 'No (N)'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-26T19:27:32', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6505737d-764b-4e14-86de-dc01d1de98fb' User entered '26 Oct 2020 19:27'	System	27 Oct 2020 02:27:37
	System	27 Oct 2020 02:27:37

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 5'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:13', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:16', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:19', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:23', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:33', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:36', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'None (0)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:52', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered 'No (N)'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-27T20:18:56', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '6f5bafb8-5db2-49b8-8040-678f942549e0' User entered '27 Oct 2020 20:18'	System	28 Oct 2020 03:18:59
	System	28 Oct 2020 03:18:59

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 6'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:40', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:46', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:54', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:01:58', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:02:02', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:02:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'None (0)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:02:14', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered 'No (N)'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-28T21:02:23', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '0def07c9-4143-491e-947e-db51d76727f0' User entered '28 Oct 2020 21:02'	System	29 Oct 2020 04:02:25
	System	29 Oct 2020 04:02:25

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
Data entry locked.	System	23 Oct 2020 21:45:33
User entered 'Day 7'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:54', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:40:57', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:01', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:06', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:08', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:11', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'None (0)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:18', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered 'No (N)'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-10-29T21:41:21', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '896bf94a-631e-4d8e-83e8-e21c5bce4a0b' User entered '29 Oct 2020 21:41'	System	30 Oct 2020 04:41:23
	System	30 Oct 2020 04:41:23

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 21:45:33

US3882049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:45:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:05:42
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 21:45:33

US3882049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:51:24
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:33:51
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Oct 2020 17:27:34

US3882049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:51:24
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:33:51
User entered '30 Oct 2020'	Lauren Vigil (b) (4)	30 Oct 2020 17:27:34

US3882049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:51:24
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:33:51
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	30 Oct 2020 17:27:34

US3882049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:51:24
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:33:51
User entered 'DENIES FEVER, CHILLS, COUGH, SORE THROAT, HEADACHE, MALAISE, N/V.'	Lauren Vigil (b) (4)	30 Oct 2020 17:27:34

US3882049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:33:51
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Oct 2020 17:27:40

US3882049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	30 Oct 2020 17:27:40

US3882049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	07 Nov 2020 16:24:27
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	06 Nov 2020 17:50:11

US3882049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:34:36
Signature has been broken.	Lauren Vigil (b) (4)	11 Nov 2020 01:01:17
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 01:01:17
User signature succeeded.	Michael Lewis (b) (4)	07 Nov 2020 16:24:27
User entered '6 Nov 2020'	Lauren Vigil (b) (4)	06 Nov 2020 17:50:11

US3882049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	07 Nov 2020 16:24:27
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	06 Nov 2020 17:50:11

US3882049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	07 Nov 2020 16:24:27
User entered empty.	Lauren Vigil (b) (4)	06 Nov 2020 17:50:11

US3882049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	07 Nov 2020 16:24:27
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	06 Nov 2020 17:50:14

US3882049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	06 Nov 2020 17:50:14

US3882049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:47:50
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	18 Feb 2021 17:02:47
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 15:02:18
User signature succeeded.	Michael Lewis (b) (4)	21 Nov 2020 00:52:58
User entered 'Yes (Y)'	Suchi Tiwari (b) (4) (b) (4)	17 Nov 2020 02:26:47

US3882049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Nov 2020 00:52:58
User entered '16 Nov 2020'	Suchi Tiwari (b) (4)	17 Nov 2020 02:26:47

US3882049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Nov 2020 00:52:58
User entered 'Contact Made (CONTACT MADE)'	Suchi Tiwari (b) (4)	17 Nov 2020 02:26:47

US3882049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Nov 2020 00:52:58
User entered empty.	Suchi Tiwari (b) (4)	17 Nov 2020 02:26:47

US3882049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Nov 2020 00:52:58
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	17 Nov 2020 02:26:54

US3882049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	17 Nov 2020 02:26:54

US3882049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'No (N)'	Lauren Vigil (b) (4)	17 Feb 2021 00:59:06

US3882049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	17 Feb 2021 00:59:06

US3882049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	17 Feb 2021 00:59:06

US3882049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'VISIT2'	System	17 Feb 2021 00:59:06

US3882049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:02:13

US3882049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '1'	System	18 Feb 2021 17:02:13

US3882049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:03:27

US3882049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '30 Nov 2020'	Lauren Vigil (b) (4)	18 Feb 2021 17:03:27

US3882049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	18 Feb 2021 17:03:27

US3882049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:03:27

US3882049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:03:38

US3882049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	18 Feb 2021 17:03:38

US3882049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:09

US3882049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '7 Dec 2020'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:09

US3882049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:09

US3882049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:04:09

US3882049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:13

US3882049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	18 Feb 2021 17:04:13

US3882049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:43

US3882049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered '14 Dec 2020'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:43

US3882049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:43

US3882049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:04:43

US3882049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:04:46

US3882049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'I'	System	18 Feb 2021 17:04:46

US3882049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'No (N)'	Lauren Vigil (b) (4)	18 Feb 2021 17:11:05

US3882049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:11:05

US3882049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:11:05

US3882049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered 'VISIT3'	System	18 Feb 2021 17:11:05

US3882049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:11:19

US3882049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '1'	System	18 Feb 2021 17:11:19

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-12-27T19:46:20', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a20c22c-c68a-4ec3-8ece-28a5f9ebe14b'	System	28 Dec 2020 03:47:22
User entered 'No (N)'	System	28 Dec 2020 03:47:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-12-27T19:47:02', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a20c22c-c68a-4ec3-8ece-28a5f9ebe14b'	System	28 Dec 2020 03:47:22
User entered 'No (N)'	System	28 Dec 2020 03:47:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2020-12-27T19:47:20', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '7a20c22c-c68a-4ec3-8ece-28a5f9ebe14b'	System	28 Dec 2020 03:47:22
User entered '27 Dec 2020 19:47:20'	System	28 Dec 2020 03:47:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-03T11:58:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ed2890b1-368c-42f9-b7c2-6b3812235d02'	System	03 Jan 2021 19:58:20
User entered 'No (N)'	System	03 Jan 2021 19:58:20
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-03T11:58:07', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ed2890b1-368c-42f9-b7c2-6b3812235d02'	System	03 Jan 2021 19:58:20
User entered 'No (N)'	System	03 Jan 2021 19:58:20
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-03T11:58:16', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ed2890b1-368c-42f9-b7c2-6b3812235d02'	System	03 Jan 2021 19:58:20
User entered '03 Jan 2021 11:58:16'	System	03 Jan 2021 19:58:20
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:12:56', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'Yes (Y)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:07', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'No (N)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:17', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'Yes (Y)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '1'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '1'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '1'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:39', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '0'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:13:54', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:14:14', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'Yes (Y)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:14:19', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-10T13:14:51', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2d6ba400-0550-474c-ad59-e7436e8075e3'	System	10 Jan 2021 21:15:01
User entered '10 Jan 2021 13:14:51'	System	10 Jan 2021 21:15:01
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-17T09:35:35', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '32fa5299-2569-4489-97a2-5594d8f89a01'	System	17 Jan 2021 17:36:07
User entered 'No (N)'	System	17 Jan 2021 17:36:07
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-17T09:35:50', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '32fa5299-2569-4489-97a2-5594d8f89a01'	System	17 Jan 2021 17:36:07
User entered 'No (N)'	System	17 Jan 2021 17:36:07
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-17T09:36:05', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '32fa5299-2569-4489-97a2-5594d8f89a01'	System	17 Jan 2021 17:36:07
User entered '17 Jan 2021 09:36:05'	System	17 Jan 2021 17:36:07
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-24T07:32:36', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cfdc943d-d172-4828-8d88-bc0bc725f47b'	System	24 Jan 2021 15:33:02
User entered 'No (N)'	System	24 Jan 2021 15:33:02
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-24T07:32:41', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cfdc943d-d172-4828-8d88-bc0bc725f47b'	System	24 Jan 2021 15:33:02
User entered 'No (N)'	System	24 Jan 2021 15:33:02
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-01-24T07:32:48', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cfdc943d-d172-4828-8d88-bc0bc725f47b'	System	24 Jan 2021 15:33:02
User entered '24 Jan 2021 07:32:48'	System	24 Jan 2021 15:33:02
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-02T07:06:08', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9084f290-482c-4bf4-b17c-3d262244f0a9'	System	02 Feb 2021 15:06:22
User entered 'No (N)'	System	02 Feb 2021 15:06:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-02T07:06:13', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9084f290-482c-4bf4-b17c-3d262244f0a9'	System	02 Feb 2021 15:06:22
User entered 'No (N)'	System	02 Feb 2021 15:06:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-02T07:06:17', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9084f290-482c-4bf4-b17c-3d262244f0a9'	System	02 Feb 2021 15:06:22
User entered '02 Feb 2021 07:06:17'	System	02 Feb 2021 15:06:22
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-08T18:10:45', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '5a197f77-0766-4fc4-a7ce-1f3480b5351e'	System	09 Feb 2021 02:17:11
User entered 'No (N)'	System	09 Feb 2021 02:17:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-08T18:10:49', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '5a197f77-0766-4fc4-a7ce-1f3480b5351e'	System	09 Feb 2021 02:17:11
User entered 'No (N)'	System	09 Feb 2021 02:17:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-08T18:10:56', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '5a197f77-0766-4fc4-a7ce-1f3480b5351e'	System	09 Feb 2021 02:17:11
User entered '08 Feb 2021 18:10:56'	System	09 Feb 2021 02:17:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-16T18:35:10', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9b52c2ab-9b66-49aa-83cb-5246567308c3'	System	17 Feb 2021 02:37:45
User entered 'No (N)'	System	17 Feb 2021 02:37:45
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-16T18:35:14', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9b52c2ab-9b66-49aa-83cb-5246567308c3'	System	17 Feb 2021 02:37:45
User entered 'No (N)'	System	17 Feb 2021 02:37:45
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-16T18:35:21', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '9b52c2ab-9b66-49aa-83cb-5246567308c3'	System	17 Feb 2021 02:37:45
User entered '16 Feb 2021 18:35:21'	System	17 Feb 2021 02:37:45
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-21T21:26:44', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e9618cd0-fdf8-49fa-a662-1ceb034e6edc'	System	22 Feb 2021 05:26:54
User entered 'No (N)'	System	22 Feb 2021 05:26:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-21T21:26:47', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e9618cd0-fdf8-49fa-a662-1ceb034e6edc'	System	22 Feb 2021 05:26:54
User entered 'No (N)'	System	22 Feb 2021 05:26:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-21T21:26:51', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e9618cd0-fdf8-49fa-a662-1ceb034e6edc'	System	22 Feb 2021 05:26:54
User entered '21 Feb 2021 21:26:51'	System	22 Feb 2021 05:26:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-28T15:03:29-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'aa5f60da-5604-47bc-b525-c6ea84d79e24'	System	28 Feb 2021 23:09:27
User entered 'No (N)'	System	28 Feb 2021 23:09:27
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-28T15:03:33-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'aa5f60da-5604-47bc-b525-c6ea84d79e24'	System	28 Feb 2021 23:09:27
User entered 'No (N)'	System	28 Feb 2021 23:09:27
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-28T15:03:42-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'aa5f60da-5604-47bc-b525-c6ea84d79e24'	System	28 Feb 2021 23:09:27
User entered '28 Feb 2021 23:03:42'	System	28 Feb 2021 23:09:27
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-07T09:49:45-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '1fa61974-ecc3-46b9-9f1e-24a5e96be102'	System	07 Mar 2021 17:50:09
User entered 'No (N)'	System	07 Mar 2021 17:50:09
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-07T09:49:59-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '1fa61974-ecc3-46b9-9f1e-24a5e96be102'	System	07 Mar 2021 17:50:09
User entered 'No (N)'	System	07 Mar 2021 17:50:09
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-07T09:50:05-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '1fa61974-ecc3-46b9-9f1e-24a5e96be102'	System	07 Mar 2021 17:50:09
User entered '07 Mar 2021 09:50:05'	System	07 Mar 2021 17:50:09
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:08:38

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-16T07:05:45-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cd34a566-3934-4a11-b82e-fab6bbf52908'	System	16 Mar 2021 14:06:06
User entered 'No (N)'	System	16 Mar 2021 14:06:06
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-16T07:05:52-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cd34a566-3934-4a11-b82e-fab6bbf52908'	System	16 Mar 2021 14:06:06
User entered 'No (N)'	System	16 Mar 2021 14:06:06
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-16T07:05:55-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'cd34a566-3934-4a11-b82e-fab6bbf52908'	System	16 Mar 2021 14:06:06
User entered '16 Mar 2021 07:05:55'	System	16 Mar 2021 14:06:06
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-21T10:09:29-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '4cf05eee-b166-45fd-80f8-b442138020ca'	System	21 Mar 2021 17:10:37
User entered 'No (N)'	System	21 Mar 2021 17:10:37
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-21T10:09:32-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '4cf05eee-b166-45fd-80f8-b442138020ca'	System	21 Mar 2021 17:10:37
User entered 'No (N)'	System	21 Mar 2021 17:10:37
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-21T10:09:36-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '4cf05eee-b166-45fd-80f8-b442138020ca'	System	21 Mar 2021 17:10:37
User entered '21 Mar 2021 10:09:36'	System	21 Mar 2021 17:10:37
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-28T10:06:05-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '02c640d4-149d-4a84-8c68-0447a6194983'	System	28 Mar 2021 17:07:59
User entered 'No (N)'	System	28 Mar 2021 17:07:59
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-28T10:06:10-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '02c640d4-149d-4a84-8c68-0447a6194983'	System	28 Mar 2021 17:07:59
User entered 'No (N)'	System	28 Mar 2021 17:07:59
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-03-28T10:06:13-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '02c640d4-149d-4a84-8c68-0447a6194983'	System	28 Mar 2021 17:07:59
User entered '28 Mar 2021 10:06:13'	System	28 Mar 2021 17:07:59
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-04T09:12:19-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e65c27cd-30ac-46e4-b7ab-9188276f2b3f'	System	04 Apr 2021 16:12:30
User entered 'No (N)'	System	04 Apr 2021 16:12:30
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-04T09:12:22-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e65c27cd-30ac-46e4-b7ab-9188276f2b3f'	System	04 Apr 2021 16:12:30
User entered 'No (N)'	System	04 Apr 2021 16:12:30
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-04T09:12:27-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'e65c27cd-30ac-46e4-b7ab-9188276f2b3f'	System	04 Apr 2021 16:12:30
User entered '04 Apr 2021 09:12:27'	System	04 Apr 2021 16:12:30
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-12T12:03:44-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ff04b0ba-cc1a-4e25-b63e-150803572061'	System	12 Apr 2021 19:05:18
User entered 'No (N)'	System	12 Apr 2021 19:05:18
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-12T12:03:49-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ff04b0ba-cc1a-4e25-b63e-150803572061'	System	12 Apr 2021 19:05:18
User entered 'No (N)'	System	12 Apr 2021 19:05:18
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-12T12:03:52-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'ff04b0ba-cc1a-4e25-b63e-150803572061'	System	12 Apr 2021 19:05:18
User entered '12 Apr 2021 12:03:52'	System	12 Apr 2021 19:05:18
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-19T18:05:38-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2351573e-9ffd-42e4-a61f-c32b5090ea65'	System	20 Apr 2021 01:10:54
User entered 'No (N)'	System	20 Apr 2021 01:10:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-19T18:05:42-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2351573e-9ffd-42e4-a61f-c32b5090ea65'	System	20 Apr 2021 01:10:54
User entered 'No (N)'	System	20 Apr 2021 01:10:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-04-19T18:05:49-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '2351573e-9ffd-42e4-a61f-c32b5090ea65'	System	20 Apr 2021 01:10:54
User entered '19 Apr 2021 18:05:49'	System	20 Apr 2021 01:10:54
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

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 (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-05-02T21:09:39-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'a00239b4-b8e8-4506-a390-2b03ea20f1a3'	System	03 May 2021 21:03:15
User entered 'No (N)'	System	03 May 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-05-02T21:09:43-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'a00239b4-b8e8-4506-a390-2b03ea20f1a3'	System	03 May 2021 21:03:15
User entered 'No (N)'	System	03 May 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-05-02T21:09:49-07:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: 'a00239b4-b8e8-4506-a390-2b03ea20f1a3'	System	03 May 2021 21:03:15
User entered '02 May 2021 21:09:49'	System	03 May 2021 21:03:15
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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Audit	User	Time (GMT)
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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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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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

Audit	User	Time (GMT)
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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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US3882049

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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)
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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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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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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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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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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US3882049

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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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[Patient Cloud Close Date & Time](#)

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Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:08:38

US3882049

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

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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)
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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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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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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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[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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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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US3882049

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[Patient Cloud Open Date & Time](#)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

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TIMEPOINT

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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

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[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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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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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
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US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

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)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
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US3882049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Have you been exposed to someone with 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Please 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 unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '25 Dec 2022 00:01'	System	20 Nov 2020 13:08:38

US3882049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:45:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:11
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Activated.	System	21 Dec 2020 18:27:19
DataPoint Inactivated.	System	17 Dec 2020 20:45:02
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:08:38
Amendment Manager: User entered '29 Dec 2022 23:59'	System	20 Nov 2020 13:08:38

US3882049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:45:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:05:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-28T15:03:59-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '1f6ea923-f941-46e0-8d43-63b83363f072'	System	28 Feb 2021 23:09:50
User entered 'No (N)'	System	28 Feb 2021 23:09:50

US3882049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:45:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:05:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F308C02B-94AE-470E-BE95-770D3F5E9E42)', Time: '2021-02-28T15:04:05-08:00', User OID: 'PatientReportedOutcome (US3882049)', ODM File OID: '1f6ea923-f941-46e0-8d43-63b83363f072' User entered '28 Feb 2021 23:04:05'	System	28 Feb 2021 23:09:50
	System	28 Feb 2021 23:09:50

US3882049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Feb 2021 17:12:08

US3882049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
Signature has been broken.	Lauren Vigil (b) (4)	26 Mar 2021 21:58:38
User entered '20 Jan 2021' reason for change: Data Entry Error	Lauren Vigil (b) (4)	26 Mar 2021 21:58:38
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered '18 Feb 2021'	Lauren Vigil (b) (4)	18 Feb 2021 17:12:08

US3882049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	18 Feb 2021 17:12:08

US3882049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:12:08

US3882049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
Signature has been broken.	Lauren Vigil (b) (4)	24 Feb 2021 18:05:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	24 Feb 2021 18:05:13
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:14:05
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:12:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:12:28
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Feb 2021 17:12:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:12:12
User entered empty.	Lauren Vigil (b) (4)	18 Feb 2021 17:12:12

US3882049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:42:08
User entered '1'	System	24 Feb 2021 18:05:13
User entered empty.	System	18 Feb 2021 17:12:12

US3882049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:33:47
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Feb 2021 18:12:33

US3882049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:33:47
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User entered '24 Feb 2021'	Lauren Vigil (b) (4)	24 Feb 2021 18:12:33

US3882049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:33:47
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
Signature has been broken.	Lauren Vigil (b) (4)	26 Mar 2021 21:59:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Lauren Vigil (b) (4)	26 Mar 2021 21:59:26
User signature succeeded.	(b) (4)	
	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Lauren Vigil (b) (4)	24 Feb 2021 18:12:33
	(b) (4)	

US3882049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:09:11
User closed query 'SC Day 119 notes that subject experienced a sprained ankle. Please record under Adverse Event and enter any associated con-meds as necessary. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:08:57
Query 'SC Day 119 notes that subject experienced a sprained ankle. Please record under Adverse Event and enter any associated con-meds as necessary. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	07 Apr 2021 21:34:19
User opened query 'SC Day 119 notes that subject experienced a sprained ankle. Please record under Adverse Event and enter any associated con-meds as necessary. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:36:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:35:20
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:33:47
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
Signature has been broken.	Lauren Vigil (b) (4)	26 Mar 2021 21:59:26
User entered 'NO ANSWER, LEFT VOICEMAIL. Second attempt 2/25 and contact made.' reason for change: Data Entry Error	Lauren Vigil (b) (4)	26 Mar 2021 21:59:26
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User entered 'No answer, left voicemail.'	Lauren Vigil (b) (4)	24 Feb 2021 18:12:33

US3882049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:34:12
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Feb 2021 18:12:40

US3882049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
User entered 'I'	System	24 Feb 2021 18:12:40

US3882049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:58
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Mar 2021 00:26:04

US3882049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:58
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
User entered '25 Mar 2021'	Lauren Vigil (b) (4)	26 Mar 2021 00:26:04

US3882049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:58
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	26 Mar 2021 00:26:04

US3882049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:58
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
User entered empty.	Lauren Vigil (b) (4)	26 Mar 2021 00:26:04

US3882049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:37:07
User signature succeeded.	Michael Lewis (b) (4)	27 Mar 2021 15:10:30
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Mar 2021 00:26:08

US3882049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:20:28
User entered 'I'	System	26 Mar 2021 00:26:08

US3882049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	28 Apr 2021 10:53:21
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Apr 2021 22:16:16

US3882049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	28 Apr 2021 10:53:21
User entered '26 Apr 2021'	Justine Velandria (b) (4)	26 Apr 2021 22:16:16

US3882049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	28 Apr 2021 10:53:21
User entered 'Contact Made (CONTACT MADE)'	Justine Velandria (b) (4)	27 Apr 2021 15:24:49
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Justine Velandria (b) (4)	26 Apr 2021 22:16:16
	(b) (4)	

US3882049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	28 Apr 2021 10:53:21
User entered 'DENIES SYMPTOMS. DENIES CHANGES IN HEALTH HISTORY OR MEDICATION LIST.' reason for change: Data Entry Error	Justine Velandria (b) (4)	27 Apr 2021 15:24:49
User entered 'LEFT A VOICEMAIL. WILL CONTINUE TO ATTEMPT CONTACT'	Justine Velandria (b) (4)	26 Apr 2021 22:16:16

US3882049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	28 Apr 2021 10:53:21
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Apr 2021 22:16:46

US3882049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'I'	System	26 Apr 2021 22:16:46

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:45:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:52:26
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:29:09
User closed query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (25NOV2020). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:53:45
Query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (25NOV2020). Please review and update accordingly.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 21:48:34
DataPoint Un-verified.	Lauren Vigil (b) (4)	19 Feb 2021 21:48:30
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 21:48:30
User entered '22 Nov 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 21:48:30
User opened query 'Per CDM: It appears that initial start date of symptoms and Contact Date are the same (25NOV2020). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:42:47
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:18:09
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 01:13:04

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:45:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:18:09
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '17:00'	Lauren Vigil (b) (4)	26 Nov 2020 01:13:04

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:45:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '22 Nov 2020 17:00'	System	19 Feb 2021 21:48:30
User entered '25 Nov 2020 17:00'	System	26 Nov 2020 01:13:04

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:45:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:18:09
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Lauren Vigil (b) (4)	26 Nov 2020 01:13:04

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:45:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:18:09
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 01:13:04

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per ETRTR, Note that Day 1 is the first day that subject presented symptoms. Please update if applicable.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 22:18:33
Query 'Per ETRTR, Note that Day 1 is the first day that subject presented symptoms. Please update if applicable.' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	11 Dec 2020 16:13:18
User opened query 'Per ETRTR, Note that Day 1 is the first day that subject presented symptoms. Please update if applicable.' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	10 Dec 2020 20:49:54
User entered 'Day 1 (Day 1)'	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
	(b) (4)	
	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30
	(b) (4)	

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:16:53
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39
User entered '1' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:16:55
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '97'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:16:57
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '103' F	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:16:58
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Moderate (Moderate)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:03
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:05
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:21
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:22
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:23
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:25
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:27
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:29
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:30
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:52
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:54
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:55
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:57
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:17:58
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (None)'	Lauren Vigil (b) (4)	26 Nov 2020 03:20:30

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Day 2 (Day 2)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:08
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '26 Nov 2020'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:15
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	(b) (4) Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:17
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '96'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:19
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '100.8' F	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:21
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:22
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Moderate (Moderate)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:25
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:46
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:44
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:41
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:50
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:18:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:19:08
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:31:39

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Day 3 (Day 3)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '27 Nov 2020'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	(b) (4) Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54
	(b) (4)	

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '96'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '100.5' F	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Moderate (Moderate)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:32:54

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Day 4 (Day 4)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '28 Nov 2020'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '96'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	01 Dec 2020 00:34:01

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '98.8' F	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:01

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Day 5 (Day 5)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '29 Nov 2020'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '97'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '98.2' F	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:34:51

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Day 6 (Day 6)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '30 Nov 2020'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User entered '0' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	09 Dec 2020 19:11:26
User signature succeeded.	(b) (4) Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '98'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '98.4' F	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'None (None)'	Lauren Vigil (b) (4)	01 Dec 2020 00:35:49

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Day 7 (Day 7)'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '01 Dec 2020'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '0'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '98'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '97.3' F	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Dec 2020 22:10:28
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:00:35

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Day 8 (Day 8)'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '02 Dec 2020'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '0'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '99'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '98.4' F	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Mild (Mild)'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:08:01
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:01:48

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Day 9 (Day 9)'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '03 Dec 2020'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '0'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '96'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '97.4' F	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:09:17
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:05:38

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
Query 'Per CDM: Per CCGs, Symptom Log must be completed for 14 days or until symptoms resolve whichever is later for participants that are confirmed SARs-CoV-2 positive based on the date of Illness Day 1. Please verify if the missing data is available, otherwise please select Assessment Not Done until Day14.' canceled (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 14:00:14
User opened query 'Per CDM: Per CCGs, Symptom Log must be completed for 14 days or until symptoms resolve whichever is later for participants that are confirmed SARs-CoV-2 positive based on the date of Illness Day 1. Please verify if the missing data is available, otherwise please select Assessment Not Done until Day14.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:11:48
User closed query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 08:03:40
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later.' answered with 'Symptoms resolved.' (Site from CRA).	Lauren Vigil (b) (4)	21 Dec 2020 17:53:31
User opened query 'Per ETRTR, Please add additional lines to record symptoms. According to protocol participants will be monitored by study investigator for a 14 day period after diagnosis, or until symptoms resolved, whatever is later.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 20:50:31
User entered 'Day 10 (Day 10)'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '04 Dec 2020'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '0'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '98'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '%'	System	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '97.5' F	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)'	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:45:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:22:12
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'None (None)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	09 Dec 2020 19:10:39
User entered empty.	Lauren Vigil (b) (4)	08 Dec 2020 22:06:16

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:37:23
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:37:25
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:50:29
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).	(b) (4), (b) (6)	30 Nov 2020 05:02:49
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
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 'Test result was positive. Adverse Events form updated' (Site from System).	Lauren Vigil (b) (4)	26 Nov 2020 03:21:55
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	26 Nov 2020 03:21:23
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:50:32
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:12
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:14
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[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)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:18:01
User closed query 'Per ETRTR, Please confirm if data entered is correct and update if needed. According to PPD Labs, covid PCR swab was collected on 25 Nov 2020.' (Site from CRA). Query 'Per ETRTR, Please confirm if data entered is correct and update if needed. According to PPD Labs, covid PCR swab was collected on 25 Nov 2020.' answered with 'updated' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	11 Dec 2020 22:17:58
	Lauren Vigil (b) (4)	11 Dec 2020 16:14:11
	(b) (4)	
	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
	(b) (4)	
User opened query 'Per ETRTR, Please confirm if data entered is correct and update if needed. According to PPD Labs, covid PCR swab was collected on 25 Nov 2020.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	10 Dec 2020 20:51:54
	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23
	(b) (4)	

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Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:17
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'West LA VA Greater Los Angeles'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:19
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:14:06
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:45:16

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'I'	System	26 Nov 2020 03:21:23

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:51:59
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:01
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:03
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:05
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

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)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:19
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:22
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:24
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:25
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '97'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:27
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 00:53:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 00:53:26
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:53:26
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 00:44:34
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:44:34
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 00:42:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 00:42:15
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:15
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 00:42:07
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

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Generated On: 12 Aug 2021 13:45:16

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:45:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

Form: Covid-19 Severity Assessment

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per CDM: Evidence of Pneumonia has Clinical Evidence recorded as NO but data is provided. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:54:19
Query 'Per CDM: Evidence of Pneumonia has Clinical Evidence recorded as NO but data is provided. Please review and update accordingly.' answered with '1F621626520' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 21:51:09
User opened query 'Per CDM: Evidence of Pneumonia has Clinical Evidence recorded as NO but data is provided. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:44:21
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:51
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	10 Dec 2020 18:07:33
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	10 Dec 2020 18:07:33
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4) (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4) (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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Generated On: 12 Aug 2021 13:45:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:44:49
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:12:55
DataPoint Un-verified.	Lauren Vigil (b) (4)	19 Feb 2021 21:51:05
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	19 Feb 2021 21:51:05
User entered empty; reason for change Data Entry Error	(b) (4) Lauren Vigil (b) (4)	19 Feb 2021 21:51:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:53
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	Lauren Vigil (b) (4)	10 Dec 2020 18:07:33
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	10 Dec 2020 18:07:33
User signature succeeded.	(b) (4) Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	(b) (4) Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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Generated On: 12 Aug 2021 13:45:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	02 Dec 2020 00:42:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

US3882049

Folder: Covid-19 Assessment 22 Nov 2020

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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)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:52:55
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Covid-19 Assessment 22 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:53:00
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:24:28

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User accepted default value 'Day 3 (Day 3)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:10
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 is duplicating with each other in EDC and Preclarus portal, please verify and update the correct sample collection date for each day and confirm in query response.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 09:39:32
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:14:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:48:21
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 is duplicating with each other in EDC and Preclarus portal, please verify and update the correct sample collection date for each day and confirm in query response.' answered with 'verified the dates are correct' (Site from DM).	Lauren Vigil (b) (4)	06 Apr 2021 17:08:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 is duplicating with each other in EDC and Preclarus portal, please verify and update the correct sample collection date for each day and confirm in query response.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:45:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample collection date is same for all the days, please verify and confirm and correct in EDC.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:29:45
Query 'Per GCL Lab Reconciliation: Saliva: Sample collection date is same for all the days, please verify and confirm and correct in EDC.' answered with 'Collection date occurred on 4DEC2020' (Site from DM).	Lauren Vigil (b) (4)	29 Mar 2021 16:33:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample collection date is same for all the days, please verify and confirm and correct in EDC.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:45:12

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 reported in Preclarus report which are not matching with EDC recorded sample dates for these days. Please review and update the date mismatch in EDC or Preclarus Portal as appropriate to reflect correct with EDC data, thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 07:45:12
	Michael Lewis (b) (4)	25 Mar 2021 23:24:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 reported in Preclarus report which are not matching with EDC recorded sample dates for these days. Please review and update the date mismatch in EDC or Preclarus Portal as appropriate to reflect correct with EDC data, thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Lauren Vigil (b) (4)	25 Mar 2021 19:30:57
	(b) (4)	
	Lauren Vigil (b) (4)	25 Mar 2021 19:29:57
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	25 Mar 2021 19:29:57
	(b) (4)	
User entered '4 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	25 Mar 2021 19:29:57
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04Dec2020 for Day 3, Day 5, Day 7 reported in Preclarus report which are not matching with EDC recorded sample dates for these days. Please review and update the date mismatch in EDC or Preclarus Portal as appropriate to reflect correct with EDC data, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:11:22
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:10:19
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' answered with 'Requisition ID: 1F621626520' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 21:50:05
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:26:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:28:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession Number: 1F60NOG' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	22 Dec 2020 00:55:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:42:34
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered '27 Nov 2020'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User accepted default value 'Day 5 (Day 5)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:23
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:14:32
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:48:24
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:40:36
User signature succeeded.	Michael Lewis (b) (4)	25 Mar 2021 23:24:25
DataPoint Un-verified.	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
	(b) (4)	
User entered '4 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:10:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' answered with '1F621626520' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 21:50:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29Nov2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:26:43

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:28:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession Number: 1F60NOG' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	22 Dec 2020 00:55:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:42:57
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered '29 Nov 2020'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User accepted default value 'Day 7 (Day 7)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:34
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:14:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:48:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:40:39
User signature succeeded.	Michael Lewis (b) (4)	25 Mar 2021 23:24:25
DataPoint Un-verified.	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
	(b) (4)	
User entered '4 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	25 Mar 2021 19:30:35
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01Dec2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:10:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01Dec2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' answered with 'requisition ID: 1F621626520' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 21:50:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01Dec2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:27:03

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:28:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Accession Number: 1F60NOG' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	22 Dec 2020 00:56:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered '01 Dec 2020'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per Lab Recon: Saliva: Sample dated 4Dec2020 is reported under Illness Visit Day 9 in EDC, however GCL same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 04:10:42
Query 'Per Lab Recon: Saliva: Sample dated 4Dec2020 is reported under Illness Visit Day 9 in EDC, however GCL same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'Correct date is 04DEC2020. Sample was not collected during a visit but during the convalescent period where the sub collected the sample at home' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Mar 2021 21:08:24
User opened query 'Per Lab Recon: Saliva: Sample dated 4Dec2020 is reported under Illness Visit Day 9 in EDC, however GCL same is reported for Day 3 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:20:04
User accepted default value 'Day 9 (Day 9)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:42
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:14:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:48:32
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:44
User signature succeeded.	Michael Lewis (b) (4)	15 Dec 2020 22:51:55
Signature has been broken.	Lauren Vigil (b) (4)	14 Dec 2020 18:14:50
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Lauren Vigil (b) (4)	14 Dec 2020 18:14:50
User signature succeeded.	(b) (4)	
	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered '03 Dec 2020'	(b) (4)	
	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User accepted default value 'Day 14 (Day 14)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:52
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'NA (COVID-19 Negative) (NA)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:14:55
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered empty.	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User accepted default value 'Day 21 (Day 21)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:15:08
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'NA (COVID-19 Negative) (NA)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:15:09
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered empty.	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:45:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per Lab Recon: Saliva: Sample dated 21Dec2020 is reported under Illness Visit Day 28 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:27:18
Query 'Per Lab Recon: Saliva: Sample dated 21Dec2020 is reported under Illness Visit Day 28 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'Day 28 tube was used to collect Day 21 sample' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Mar 2021 21:09:40
User opened query 'Per Lab Recon: Saliva: Sample dated 21Dec2020 is reported under Illness Visit Day 28 in EDC, however GCL same is reported for Day 21 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:24:27
User accepted default value 'Day 28 (Day 28)'	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:45:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:15:15
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 21:32:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 21:32:10
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'NA (COVID-19 Negative) (NA)'	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:15:17
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 21:32:06
User entered '21 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 21:32:06
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered empty.	Lauren Vigil (b) (4)	07 Dec 2020 20:28:37

US3882049

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 08:05:37
User closed query 'Per ETRTR, Please complete Vitals Signs page.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 08:05:34
Query 'Per ETRTR, Please complete Vitals Signs page.' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	17 Dec 2020 00:13:40
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 16:48:07
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:47:55
User opened query 'Per ETRTR, Please complete Vitals Signs page.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 20:52:49
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 01:09:59

US3882049

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:56:16
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 05:09:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	14 Dec 2020 18:14:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:27:42
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4) (b) (4)	26 Nov 2020 01:09:59

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[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 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:55:53
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	26 Nov 2020 01:09:59

US3882049

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'SICKD1'	System	26 Nov 2020 01:09:59

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:56:54
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:57:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 23:57:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 23:57:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:56:57
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:56:52
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:58:14
User entered '25 Nov 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 23:58:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Dec 2020 23:57:03
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57
	(b) (4)	

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:56:50
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:58:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 23:58:14
User entered '16:15' reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 23:58:14
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:57:03
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '25 Nov 2020 16:15'	System	16 Dec 2020 23:58:14
User entered empty.	System	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:58:55
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:58:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 23:58:14
User entered '72' in reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 23:58:14
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:57:03
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57
DataPoint set to visible.	System	26 Nov 2020 01:09:59

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:58:58
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:58:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 23:58:14
User entered '194' lb reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 23:58:14
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 23:57:03
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57
DataPoint set to visible.	System	26 Nov 2020 01:09:59

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:00
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '103' F	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:03
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:12
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered empty.	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:07
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '102'	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'bpm'	System	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:11
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '18'	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'breaths/min'	System	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:14
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '117'	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 01:59:16
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '75'	Lauren Vigil (b) (4)	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	16 Dec 2020 23:56:57

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:09:27
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 01:10:13

US3882049

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 22:05:02
User closed query 'Respiratory system on physical exam is marked as 'abnormal' however no respiratory condition is noted on Medical History or Adverse Event page. Please update or have the Investigator note the finding as NCS. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 22:04:59
Query 'Respiratory system on physical exam is marked as 'abnormal' however no respiratory condition is noted on Medical History or Adverse Event page. Please update or have the Investigator note the finding as NCS. ' answered with 'This is attributed to the active COVID 19 infection the participant had' (Site from CRA).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 21:51:56
User opened query 'Respiratory system on physical exam is marked as 'abnormal' however no respiratory condition is noted on Medical History or Adverse Event page. Please update or have the Investigator note the finding as NCS. ' (Site from CRA).	(b) (4), (b) (6)	12 Feb 2021 04:12:15
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4) (b) (4)	26 Nov 2020 01:10:13

US3882049

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:45:16

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:12:34
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number: 1F60NOG' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:18:09
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 21:19:45
User signature succeeded.	(b) (4), (b) (6)	04 Dec 2020 03:40:55
User entered 'Yes (Y)'	Michael Lewis (b) (4) Lauren Vigil (b) (4) (b) (4)	26 Nov 2020 19:00:35 26 Nov 2020 01:10:26

US3882049

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:12:34
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 01:10:26

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:09
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User closed query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	21 Dec 2020 21:39:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	21 Dec 2020 21:39:55
User opened query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	21 Dec 2020 21:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	21 Dec 2020 21:39:49

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:09
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:42:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	01 Feb 2021 21:32:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 10:00:27
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '21 Dec 2020'	Lauren Vigil (b) (4) (b) (4)	21 Dec 2020 21:39:49

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:09
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User closed query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	21 Dec 2020 21:39:55
User opened query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	21 Dec 2020 21:39:49
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	21 Dec 2020 21:39:49

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'SICKD28'	System	21 Dec 2020 21:39:49

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '21 Dec 2020'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '11:28'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '21 Dec 2020 11:28'	System	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:22
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '72' in	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58
DataPoint set to visible.	(b) (4) System	21 Dec 2020 21:39:55

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:21
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '194' lb	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58
DataPoint set to visible.	(b) (4) System	21 Dec 2020 21:39:55

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '98.6' F	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered empty.	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:28
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '78'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'bpm'	System	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:29
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '16'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'breaths/min'	System	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:31
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '126'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:33
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '70'	Lauren Vigil (b) (4)	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	21 Dec 2020 21:41:58

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:45
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	21 Dec 2020 21:42:42

US3882049

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:45
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '21 Dec 2020'	Lauren Vigil (b) (4)	21 Dec 2020 21:42:42

US3882049

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:45:16

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:36:03
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	21 Dec 2020 21:42:49

US3882049

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:45:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:36:03
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User entered '21 Dec 2020'	Lauren Vigil (b) (4)	21 Dec 2020 21:42:49

US3882049

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

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:10
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:51:57

US3882049

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

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:10
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Justine Velandria (b) (4)	26 Jan 2021 20:51:57

US3882049

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

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[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 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:10
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Clinic (Clinic)'	Justine Velandria (b) (4)	26 Jan 2021 20:51:57

US3882049

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

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 20:51:57

US3882049

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User closed query 'Please enter the date subject signed updated consent. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 04:02:56
User signature succeeded.	Michael Lewis (b) (4)	13 Mar 2021 13:03:02
Query 'Please enter the date subject signed updated consent. ' answered with 'Updated.' (Site from CRA).	Lauren Vigil (b) (4)	11 Mar 2021 17:47:39
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	11 Mar 2021 17:47:35
	(b) (4)	
User entered '6 Jan 2021' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Mar 2021 17:47:35
	(b) (4)	
User opened query 'Please enter the date subject signed updated consent. ' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 06:26:08
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '24 Dec 2020'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	13 Mar 2021 13:03:02
User entered '0'	Lauren Vigil (b) (4)	11 Mar 2021 17:47:35
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:35:59

US3882049

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25

US3882049

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User closed query 'Please provide answer.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 04:02:58
User signature succeeded.	Michael Lewis (b) (4)	13 Mar 2021 13:03:02
Query 'Please provide answer.' answered with 'Updated.' (Site from CRA).	Lauren Vigil (b) (4)	11 Mar 2021 20:22:15
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Mar 2021 20:22:06
	(b) (4)	
User entered empty.	Lauren Vigil (b) (4)	11 Mar 2021 17:47:35
	(b) (4)	
User opened query 'Please provide answer.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 06:26:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:35:59

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'mRNA-1273 (mRNA-1273)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'mRNA-1273 (mRNA-1273)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25

US3882049

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Not Administered (NA)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:29
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:25

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	26 Jan 2021 20:52:25

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

Form: Unblinding

Generated On: 12 Aug 2021 13:45:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'I'	System	26 Jan 2021 20:52:25

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:44
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:45
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Jan 2021 20:22:26
DataPoint set to visible.	System	26 Jan 2021 20:52:25

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:44
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:45
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Jan 2021 20:22:26
DataPoint set to visible.	System	26 Jan 2021 20:52:25

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '10:30'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '6 Jan 2021 10:30'	System	27 Jan 2021 20:22:26

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '97.7' F	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered empty.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '65'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'bpm'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '15'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'breaths/min'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '122'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	27 Jan 2021 20:22:26

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '75'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	27 Jan 2021 20:22:26

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:44
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:51:45
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered missing code ND - Not Done.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:45:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered empty.	System	27 Jan 2021 20:22:26
DataPoint set to visible.	System	26 Jan 2021 20:52:25

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '11:55'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '6 Jan 2021 11:55'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '97.2' F	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered empty.	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '58'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'bpm'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '15'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'breaths/min'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '129'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '77'	Lauren Vigil (b) (4)	27 Jan 2021 20:22:26
	(b) (4)	

US3882049

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mmHg'	System	27 Jan 2021 20:22:26

US3882049

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:52:45
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:30:39
	(b) (4)	

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:52:45
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:30:39
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered empty.	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered empty.	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'mRNA-1273'	System	27 Jan 2021 20:23:14
DataPoint set to visible.	System	26 Jan 2021 20:52:25

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '11:25'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '6 Jan 2021 11:25'	System	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Left Arm (LEFT ARM)'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:06
User entered 'ONCE'	System	27 Jan 2021 20:23:14

US3882049

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

Form: Exposure

Generated On: 12 Aug 2021 13:45:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 20:23:14

US3882049

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:16
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:27

US3882049

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:16
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:27

US3882049

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:16
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '10:48'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:27

US3882049

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '6 Jan 2021 10:48'	System	27 Jan 2021 20:23:27

US3882049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:36
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:49

US3882049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:36
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:49

US3882049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:45:16

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:36
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '10:45'	Lauren Vigil (b) (4)	27 Jan 2021 20:23:49
	(b) (4)	

US3882049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '6 Jan 2021 10:45'	System	27 Jan 2021 20:23:49

US3882049

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

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:42
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:52:35
	(b) (4)	

US3882049

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

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:54:19
User entered '1'	System	26 Jan 2021 20:52:35

US3882049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:20:56
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:53:56
	(b) (4)	

US3882049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:20:56
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '13 Jan 2021'	Justine Velandria (b) (4)	26 Jan 2021 20:53:56

US3882049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:20:56
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Contact Made (CONTACT MADE)'	Justine Velandria (b) (4) (b) (4)	26 Jan 2021 20:53:56

US3882049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:45:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:20:56
User closed query 'Per DM CLR: Review specified comment, + PAIN AT INJECTION SITE, CHILLS, AND FEVER AT 103 F. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:19:06
Query 'Per DM CLR: Review specified comment, + PAIN AT INJECTION SITE, CHILLS, AND FEVER AT 103 F. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'unknown, team has not received comprehensive instruction on how to report reactogenicity in OL phase' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	01 Mar 2021 16:49:19
User opened query 'Per DM CLR: Review specified comment, + PAIN AT INJECTION SITE, CHILLS, AND FEVER AT 103 F. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 15:03:22
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered '+ pain at injection site, chills, and fever at 103 F'	Justine Velandria (b) (4) (b) (4)	26 Jan 2021 20:53:56

US3882049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:21:04
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 03:25:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	26 Jan 2021 20:54:01
	(b) (4)	

US3882049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'I'	System	26 Jan 2021 20:54:01

US3882049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:45:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '1'	System	26 Jan 2021 20:54:01
DataPoint set to visible.	System	26 Jan 2021 20:54:01

US3882049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:26
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Feb 2021 17:51:44

US3882049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:26
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '3 Feb 2021'	Lauren Vigil (b) (4)	08 Feb 2021 17:51:44

US3882049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[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 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:26
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	08 Feb 2021 17:51:44

US3882049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:45:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'OLD29'	System	08 Feb 2021 17:51:44

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '3 Feb 2021'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '11:46'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '3 Feb 2021 11:46'	System	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '98.8' F	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered empty.	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '69'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'bpm'	System	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '16'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'breaths/min'	System	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '124'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:16:56
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '84'	Lauren Vigil (b) (4)	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered 'mmHg'	System	08 Feb 2021 17:52:47

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:45:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

US3882049

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:45:11
User closed query 'Please confirm with (b) (6) if all systems were reviewed during the physical exam? All boxes on source are not checked as reviewed. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 18:44:21
Query 'Please confirm with (b) (6) if all systems were reviewed during the physical exam? All boxes on source are not checked as reviewed. ' answered with 'All systems were reviewed.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:06:46
User opened query 'Please confirm with (b) (6) if all systems were reviewed during the physical exam? All boxes on source are not checked as reviewed. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 18:19:01
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:44
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:06
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4) (b) (4)	08 Feb 2021 17:53:02

US3882049

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:45:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:06
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '3 Feb 2021'	Lauren Vigil (b) (4)	08 Feb 2021 17:53:02

US3882049

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:33
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Feb 2021 17:53:20

US3882049

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:33
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '3 Feb 2021'	Lauren Vigil (b) (4)	08 Feb 2021 17:53:20

US3882049

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:17:33
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
User entered '12:03'	Lauren Vigil (b) (4)	08 Feb 2021 17:53:20

US3882049

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '3 Feb 2021 12:03'	System	08 Feb 2021 17:53:20

US3882049

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:45:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User closed query 'Per CDM Re-Query: Site response noted; however, please confirm if these "Solicited Reactions from the Vaccine" are reportable as AEs per protocol. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 04:38:51
Query 'Per CDM Re-Query: Site response noted; however, please confirm if these "Solicited Reactions from the Vaccine" are reportable as AEs per protocol. Else clarify. Thank you.' answered with 'No' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	30 Mar 2021 20:09:52
User opened query 'Per CDM Re-Query: Site response noted; however, please confirm if these "Solicited Reactions from the Vaccine" are reportable as AEs per protocol. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:59:55
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 82. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:59:55
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 82. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject was experiencing solicited reactions from the vaccine.' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	26 Mar 2021 20:08:00
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 82. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:40:19
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:47:01

US3882049

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:45:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:25:21

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:44:54
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:10
User entered 'USA-US095-2020-mRNA-1273-P301000001'	System	02 Dec 2020 14:01:05
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 14:01:05

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:44:56
User closed query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:36:36
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
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)	10 Dec 2020 16:23:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 16:23:55
Data point term sent to Coder	System	10 Dec 2020 16:22:25
Query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	10 Dec 2020 16:21:40
Coding entries removed.	(b) (4)	
	Lauren Vigil (b) (4)	10 Dec 2020 16:21:35
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	10 Dec 2020 16:21:35
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	Lauren Vigil (b) (4)	10 Dec 2020 16:21:35
User opened query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 13:39:11
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
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)	26 Nov 2020 03:30:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 03:30:01
Data point term sent to Coder	System	26 Nov 2020 03:28:38
User entered 'COVID POSITIVE'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:44:59
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:45:01
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:45:04
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:45:07
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:47
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered empty.	System	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:46:30
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Dec 2020 22:41:40
Signature has been broken.	Lauren Vigil (b) (4)	07 Dec 2020 22:41:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Lauren Vigil (b) (4)	07 Dec 2020 22:41:40
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
	System	07 Dec 2020 22:41:32
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:41
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
User closed query 'PV Query: Please clarify event end date considering that symptoms resolved on 03Dec2020 and event was reported as resolved on 07Dec2020.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:28:21
Query 'PV Query: Please clarify event end date considering that symptoms resolved on 03Dec2020 and event was reported as resolved on 07Dec2020.' answered with 'updated' (Site from Safety).	Lauren Vigil (b) (4)	30 Dec 2020 20:31:25
Signature has been broken.	(b) (4)	
User entered '3 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	30 Dec 2020 20:31:19
User opened query 'PV Query: Please clarify event end date considering that symptoms resolved on 03Dec2020 and event was reported as resolved on 07Dec2020.' (Site from Safety).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	23 Dec 2020 19:56:28
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 22:41:32
Signature has been broken.	Lauren Vigil (b) (4)	07 Dec 2020 22:41:32
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Lauren Vigil (b) (4)	07 Dec 2020 22:41:32
User signature succeeded.	(b) (4)	
User entered empty.	System	07 Dec 2020 22:41:18
	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
	(b) (4)	
	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:43
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:29:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:28:46
User entered empty.	System	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:45
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:46:41
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'No (N)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:46:45
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:46:47
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:46:49
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:51
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:52
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:54
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:55
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:57
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:54:59
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

US3882049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:01
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:02
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:04
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:10
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
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)	18 Dec 2020 06:10:30
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:24:06
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 'updated' (Site from System).	Lauren Vigil (b) (4)	16 Dec 2020 20:01:16
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Lauren Vigil (b) (4)	16 Dec 2020 20:00:50
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	16 Dec 2020 20:00:05
Signature has been broken.	Lauren Vigil (b) (4)	16 Dec 2020 20:00:05
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	16 Dec 2020 20:00:05
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 14:29:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:28:32
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'we're waiting for further clarification from sponsor on how to proceed' (Site from Safety).	Lauren Vigil (b) (4)	07 Dec 2020 22:51:21
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:29:17
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Signature has been broken.	Lauren Vigil (b) (4)	01 Dec 2020 18:25:22
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Dec 2020 18:25:22
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'None (NONE)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:13
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'l'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:15
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:16
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered '0'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:18
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:28:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Lauren Vigil (b) (4)	07 Dec 2020 22:41:53
Signature has been broken.	Lauren Vigil (b) (4)	07 Dec 2020 22:41:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	07 Dec 2020 22:41:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:29:01
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:21
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered empty.	Lauren Vigil (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 00:55:30
User closed query 'PV Query: Please confirm if the subject was admitted to the hospital.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:29:04
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)	08 Dec 2020 22:28:54
Query 'PV Query: Please confirm if the subject was admitted to the hospital.' answered with 'subject was not admitted to hospital' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 22:42:27
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 was provided' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	07 Dec 2020 22:42:18
User opened query 'PV Query: Please confirm if the subject was admitted to the hospital.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 22:29:28
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)	07 Dec 2020 22:28:38
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 19:00:35
User entered 'Subject presented to ED for Covid test. Test was positive and study team initiated illness visit.'	Lauren Vigil (b) (4) (b) (4)	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '0'	System	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '1'	System	26 Nov 2020 03:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:45:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Sprained ankle - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 21:35:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 21:35:21
Data point term sent to Coder	System	07 Apr 2021 21:34:17
User entered 'Sprained Ankle'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '20 Jan 2021'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered empty.	System	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Apr 2021 21:33:49
User entered '28 Feb 2021' reason for change: Data Entry Error	Lauren Vigil (b) (4)	07 Apr 2021 21:33:49
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Apr 2021 21:33:23
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered empty.	System	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered 'I'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered '0'	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 21:33:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 21:33:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lauren Vigil (b) (4)	07 Apr 2021 21:33:49
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 21:33:23
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	08 Apr 2021 16:08:41
User entered empty.	Lauren Vigil (b) (4)	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '0'	System	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '0'	System	07 Apr 2021 21:33:23

US3882049

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:45:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:45:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:37:33
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:37:43

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:40:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 23:40:25
Data point term sent to Coder	System	27 Oct 2020 23:39:38
User entered 'Rosuvastatin'	Suchi Tiwari (b) (4) (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'No (N)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Hyperlipidemia'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered '40'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'mg (mg)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'once daily (QD)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Oral (ORAL)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'l'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered empty.	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 06:38:16
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:34:35
User entered 'No (N)'	Suchi Tiwari (b) (4)	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '1'	System	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '1'	System	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:45:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User entered '804 (804)'	System	27 Oct 2020 23:38:48

US3882049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:45:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:12:55
User entered 'No (N)'	Lauren Vigil (b) (4)	18 Feb 2021 17:13:00

US3882049

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:45:16

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 22:19:15
User closed query 'Per ETRTR, according to IRT subject status is Randomized but Dosing Discontinuation page is completed. Please ensure to update IRT status as applicable.' (Site from CRA).	(b) (4), (b) (6)	11 Dec 2020 22:19:02
Query 'Per ETRTR, according to IRT subject status is Randomized but Dosing Discontinuation page is completed. Please ensure to update IRT status as applicable.' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	11 Dec 2020 16:16:55
User opened query 'Per ETRTR, according to IRT subject status is Randomized but Dosing Discontinuation page is completed. Please ensure to update IRT status as applicable.' (Site from CRA).	(b) (4)	
User entered '25 Nov 2020'	(b) (4), (b) (6)	10 Dec 2020 20:42:20
	Lauren Vigil (b) (4)	09 Dec 2020 23:37:13
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:45:16

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:29:07
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'Due to SARS-COV-2 (COVID)'	Lauren Vigil (b) (4)	09 Dec 2020 23:37:13

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:45:16

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)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:29:08
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered empty.	Lauren Vigil (b) (4)	09 Dec 2020 23:37:13

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User closed query 'Per CDM : Please provide Data Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 05:31:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 05:31:27
Query 'Per CDM : Please provide Data Otherwise, clarify.' answered with 'Participant is still enrolled in study. Dose was discontinued due to COVID illness' (Site from DM).	Lauren Vigil (b) (4)	22 Dec 2020 21:22:34
User opened query 'Per CDM : Please provide Data Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 07:45:28
Query 'Data is required. Please complete.' answered with 'no data needed' (Site from System).	Lauren Vigil (b) (4)	21 Dec 2020 18:27:30
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:27:19
Signature has been broken.	Lauren Vigil (b) (4)	21 Dec 2020 18:27:19
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	21 Dec 2020 18:27:19
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
User closed query 'Per CDM : Please provide Data Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 05:31:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 05:31:39
Query 'Per CDM : Please provide Data Otherwise, clarify. ' answered with 'Participant is still enrolled in study. Dose was discontinued due to COVID illness' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	22 Dec 2020 21:22:39
User opened query 'Per CDM : Please provide Data Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 07:45:50
Query 'Data is required. Please complete.' answered with 'no data needed' (Site from System).	Lauren Vigil (b) (4) (b) (4)	21 Dec 2020 18:27:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 18:27:19
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	21 Dec 2020 18:27:19
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4) (b) (4)	21 Dec 2020 18:27:19
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered 'Other (OTHER)'	Lauren Vigil (b) (4) (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

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)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	25 Dec 2020 22:22:52
Signature has been broken.	Lauren Vigil (b) (4)	21 Dec 2020 18:27:19
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	21 Dec 2020 18:27:19
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	17 Dec 2020 20:45:24
User entered 'due to SARS-COV-2' reason for change: Data Entry Error	Lauren Vigil (b) (4)	17 Dec 2020 20:45:24
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	17 Dec 2020 20:45:02
User entered empty.	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered empty.	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered empty.	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered empty.	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:45:16

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered empty.	Lauren Vigil (b) (4)	17 Dec 2020 20:45:02

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'USA-US095-2020-MRNA-1273-P301000001'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Michael'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Lewis'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:03
User entered '11301 Wilshire Blvd'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:05
User entered 'Los Angeles'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07
	(b) (4)	

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:06
User entered 'CA'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:09
User entered '90073'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'US'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
Signature has been broken.	System	05 Jan 2021 14:28:46
User entered '4'	System	05 Jan 2021 14:28:46
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
Signature has been broken.	System	17 Dec 2020 16:24:24
User entered '3'	System	17 Dec 2020 16:24:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	System	08 Dec 2020 22:29:47
User entered '2'	System	08 Dec 2020 22:29:47
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'USA-US095-2020-MRNA-1273-P301000001'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Michael'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Lewis'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:03
User entered '11301 Wilshire Blvd'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:05
User entered 'Los Angeles'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07
	(b) (4)	

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:06
User entered 'CA'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:09
User entered '90073'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'US'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
Signature has been broken.	System	05 Jan 2021 14:28:46
User entered '4'	System	05 Jan 2021 14:28:46
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
Signature has been broken.	System	17 Dec 2020 16:24:24
User entered '3'	System	17 Dec 2020 16:24:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	System	08 Dec 2020 22:29:47
User entered '2'	System	08 Dec 2020 22:29:47
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:45:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '02/Dec/2020 14:01'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:45:16

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:59
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'USA-US095-2020-MRNA-1273-P301000001'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Michael'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Lewis'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:03
User entered '11301 Wilshire Blvd'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:05
User entered 'Los Angeles'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:06
User entered 'CA'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:09
User entered '90073'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'US'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
Signature has been broken.	System	05 Jan 2021 14:28:46
User entered '4'	System	05 Jan 2021 14:28:46
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
Signature has been broken.	System	17 Dec 2020 16:24:24
User entered '3'	System	17 Dec 2020 16:24:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	System	08 Dec 2020 22:29:47
User entered '2'	System	08 Dec 2020 22:29:47
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:45:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:43:04
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered '08/Dec/2020 17:29'	System	08 Dec 2020 22:29:47

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:45:16

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:24:14
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:42
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 22:29:47

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'USA-US095-2020-MRNA-1273-P301000001'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Michael'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Lewis'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:03
User entered '11301 Wilshire Blvd'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:05
User entered 'Los Angeles'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:06
User entered 'CA'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:09
User entered '90073'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07
	(b) (4)	

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'US'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
Signature has been broken.	System	05 Jan 2021 14:28:46
User entered '4'	System	05 Jan 2021 14:28:46
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
Signature has been broken.	System	17 Dec 2020 16:24:24
User entered '3'	System	17 Dec 2020 16:24:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	System	08 Dec 2020 22:29:47
User entered '2'	System	08 Dec 2020 22:29:47
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:45:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:39
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered '17/Dec/2020 16:24'	System	17 Dec 2020 16:24:24

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:45:16

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:41
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 14:28:34
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 16:24:24

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'USA-US095-2020-MRNA-1273-P301000001'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:41:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'No (N)'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Michael'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:07
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:01:25
User entered 'Lewis'	System	02 Dec 2020 14:01:05

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:03
User entered '11301 Wilshire Blvd'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:05
User entered 'Los Angeles'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07
	(b) (4)	

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:06
User entered 'CA'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:09
User entered '90073'	Lauren Vigil (b) (4)	08 Feb 2021 20:34:07

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:42:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 22:29:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered 'US'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:45:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
Signature has been broken.	System	05 Jan 2021 14:28:46
User entered '4'	System	05 Jan 2021 14:28:46
User signature succeeded.	Michael Lewis (b) (4)	18 Dec 2020 01:56:17
Signature has been broken.	System	17 Dec 2020 16:24:24
User entered '3'	System	17 Dec 2020 16:24:24
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 22:12:52
Signature has been broken.	System	08 Dec 2020 22:29:47
User entered '2'	System	08 Dec 2020 22:29:47
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 02:03:05
User entered '1'	System	02 Dec 2020 14:01:31

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:45:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:46
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
User entered '05/Jan/2021 14:28'	System	05 Jan 2021 14:28:46

US3882049

Folder: SAE USA-US095-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:45:16

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 04:23:48
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:42:23
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 14:28:46